# EXHIBIT 1

Whitelaw Compliance Group, LLC.

# Examination of Compliance Standards for Opioid Manufacturers and Distributors

| Prepared For | Prepared By |
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| UNITED STATES DISTRICT COURT<br>FOR THE<br>NORTHERN DISTRICT OF OHIO, EASTERN DIVISION<br><br>*IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION*<br><br>Case No. 18-OP-45132 (N.D. Ohio)<br>MDL No. 2804<br>Case No. 17-md-2804<br>Judge Dan Aaron Polster | Dr. Seth B. Whitelaw<br><br>President & CEO<br>Whitelaw Compliance Group, LLC.<br><br>April 15, 2019 |

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# PART I: Qualifications, Scope & Methodology

## 1 Qualifications

For the past 30 years, I have worked in the life sciences industry as a food and drug attorney, compliance officer, compliance consultant and professor. In addition to my J.D., I have an LL.M. in Administrative Law and an S.J.D. in Health Law. Consequently, I have extensive experience working with and interpreting legislation, statutes, regulations and guidance documents.

Since 1993, I have designed, built, and run four separate corporate compliance programs for both pharmaceutical and medical device manufacturers (C.R. Bard, Inc., SmithKline Beecham Pharmaceuticals NA, GlaxoSmithKline R&D, Misonix, Inc.). I also teach monitoring and auditing to law students and working professionals, who are enrolled in Mitchell Hamline School of Law's Healthcare Compliance Certificate program.

As a consultant for Deloitte and now my own firm, I have assessed the effectiveness of numerous U.S. and international compliance programs and their ability to detect and prevent violations of the various legal, regulatory and industry standards that govern life science company operations. In addition to assessing or developing the full compliance program, I have assessed and helped develop controls in numerous discrete areas including, but not limited to:

- pharmaceutical sampling,
- payments to and services from healthcare professionals ("HCPs"),
- product diversion controls ("grey market"),
- laboratory controlled substances controls,
- promotional material claims and use,

- third-party qualification, contracting and use, and
- medical affairs unsolicited request systems.

As an in-house compliance officer, I have conducted many audits and internal investigations directed at uncovering specific misconduct by individuals at all levels of the organization. These investigations have involved sample diversion, product diversion, clinical trial fraud, bribery and corruption, theft and misuse of human biospecimens, and the falsification of domestic and international regulatory documents (submissions, reports, certifications, licenses, import/export documents, etc.).

None of the organizations reviewed in this report have employed me or engaged the services of me and my firm. For my services on this project, I am billing $400 per hour. My compensation is not dependent on my testimony or on the outcome of this case. All my opinions offered in this report are offered to a reasonable degree of certainty. Also, I reserve the right to modify or supplement my conclusions as additional information becomes available to me, or as I perform further analyses.

# 2 Scope & Methodology

## 2.1 Scope

As an expert in the design, implementation, and operation of compliance programs in the life science industry, I was retained to examine, review and discuss:

1. The relevant standards surrounding the design, implementation, and operation of corporate and controlled substances compliance programs for the pharmaceutical industry.[1]
2. The application of those standards to manufacturers and distributors[2] of controlled substances.
3. The effectiveness of the compliance programs for five distributors and one manufacturer of prescription opioid medicinal products based upon available documentation from 1996 to 2018 ("review period").

[1] The term pharmaceutical industry is used to encompass both pharmaceutical manufacturers ("marketing defendants") and the distributors of finished pharmaceutical products to physicians, hospitals, clinics and pharmacies ("distributor defendants").

[2] Within the pharmaceutical supply chain from manufacturer to patient, pharmaceutical distributors occupy the mid-point of the chain. Thus, at the most basic level, distributors handle the logistics of getting medicinal products from the manufacturers to the local pharmacies (including hospitals and clinics) that dispense or fill the patient's prescription obtained from a licensed prescriber (doctor, dentist, nurse practitioner, physician's assistant, etc.).

## 2.2 Methodology

The manufacturers and distributors of opioids (listed as Schedule II or III controlled substances) reviewed in this report can be further categorized into groups by the type of business model. As a result, there are three different groups reviewed in this report.

- Group 1 ("G1") distributors have a standard, "pure" distribution business model, which only involves distributing pharmaceutical products and providing other ancillary data and logistical services (not in the scope of this review). These distributors, McKesson, Cardinal Health and AmerisourceBergen, also are known as the "Big Three."
- The Group 2 ("G2") distributors have a standard business model that involves embedding distribution operations within a large, national pharmacy chain that supplied only its own pharmacies with opioid products. This group of distributors also utilize the G1 distributors to ensure an uninterrupted supply of opioids to their pharmacies or to handle Schedule II controlled substances. The G2 distributors examined are CVS and Walgreens.
- The Manufacturer Group produce the finished opioid products and typically sell in bulk quantities to the G1 distributors to supply retail pharmacy outlets. Mallinckrodt was sole member of this group.

Based on my experience and expertise outlined above, I can fairly evaluate the compliance controls employed by manufacturers and distributors and render opinions on whether they are aligned with regulatory requirements, expectations and leading industry practices, as well as whether they can be considered effective. My approach to this review utilized the same methodology I have used during the last 30 years when auditing or investigating compliance issues.

For all three groups in order to gain an understanding of each company's corporate compliance and anti-diversion programs during the review period, I conducted a detailed examination of both publicly available statements and documents, and documents produced by the manufacturers and distributors in the course of this case. In the course of preparing this report, that information included, but was not limited to:

- company websites and press releases;
- government enforcement settlement documents, including inspection reports, Memoranda of Agreement;
- government correspondence to and from the company;
- company policies and procedures;
- organization charts;
- reports of compliance breaches and investigations;
- compliance training materials;
- committee reports and presentation materials;
- audit and other internal review reports; and
- third party consultant reports.

That information examined was then evaluated against the standards described in Part II of this report.

I also examined relevant data showing opioid shipments as well as suspicious orders reported to the DEA by the distributors and manufacturers during the review period. This data pertained not only to Summit and Cuyahoga

Counties, but also other jurisdictions as well such as West Virginia. Although Summit and Cuyahoga Counties are the primary focus of this report, these anti-diversion programs were national programs and not state or county specific. Therefore, I have reviewed and evaluated activity that also occurred outside of Summit and Cuyahoga Counties. This is the same approach taken by the House Energy and Commerce Committee in its 2018 report.[3]

Finally, I also consulted with James Rafalski, a retired DEA diversion investigator, who also is an expert in this case. I discussed with him how the DEA applies the Controlled Substances Act, the accompanying regulations and the Agency's guidance when inspecting the controlled substances anti-diversion efforts of a manufacturer or a distributor, including their suspicious order monitoring programs. We also discussed what the DEA generally considers to constitute an effective controlled substances compliance program for a prudent registrant.

# PART II: Compliance Program Standards

## 3 Understanding the Context

This part of the report discusses the compliance standards that pertain to the marketing, sale, and distribution of prescription opioid products. Although the focus of this report is on prescription opioid products, and with good reason given the current public health crisis,[4] most of the applicable compliance programs standards are not opioid specific. Likewise, these standards are publicly available and routinely accessed by compliance

[3] *See* U.S. House Energy & Commerce Committee Report, *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, 115th Cong., 9 (Dec. 19, 2018) (While focused on a narrow part of West Virginia, the report raises grave concerns about practices by the distributors and the DEA nationwide.) ["W.Va. Red Flags Report"].

[4] *See* Discussion *infra* at Appendix A, Figure 1.

professionals in the pharmaceutical industry to evaluate and develop industry-specific corporate and controlled substances compliance programs.

## 3.1 General Overview of Compliance

Within the pharmaceutical industry, the term "compliance" is used to describe a vast array of functions and activities. For example, there is "Quality Compliance," "Regulatory or FDA Compliance," controlled substances compliance (a.k.a. "Suspicious Order Monitoring" or "SOM") and others. However they are described, these functions are focused on integrating into a company's business fabric, values and principles, as well as societal expectations expressed through laws, regulations, and industry standards of conduct.[5] Therefore, compliance is not simply focused on legal and regulatory compliance to create an organizational framework to detect and prevent illegal or unethical conduct, but with establishing and promoting a corporate culture that manages risk, protects the company's reputation, and above all strives to do no harm (*primum non nocere*). This is the true essence of "compliance."

A primary function of the corporate compliance (a.k.a. "Big C Compliance") program is oversight and coordination of the other internal compliance functions to minimize duplication, together with providing an organization's Board of Directors and senior management a contextualized picture of the organization's compliance posture at a given moment of time, which highlights areas where the organization's behavior can improve.

This case concerns compliance standards for the marketing, sale, and distribution of prescription opioid products. While all prescription products carry some degree of risk, prescription opioid products, even when used for legitimate medicinal purposes, pose a special level of risk given their propensity to cause harm through addiction and the risk of diversion into the "black market" of illegal drugs.

This is evidenced by the fact that not only do prescription opioids require a prescription from a licensed medical professional, but they also have additional government-imposed controls surrounding the distribution and dispensing of these products. Therefore, it is expected that any company involved in the marketing, sale, or distribution of these products maintains a robust and effective compliance function in accordance with values, principles and societal expectations that strive to do no harm by ensuring these products are obtainable by legitimate patients while maintaining efforts to detect and prevent illegal diversion. As an ancillary benefit, such efforts can reduce the company's exposure to legal and reputational risk helping the company fulfill its "contract" with shareholders to protect their investments and maintain confidence in the company.

This expectation to maintain a robust and effective compliance program is true even if there were no laws or regulations governing the marketing, sale, and distribution of prescription opioid products (e.g., the Controlled Substances Act). It also is an important "compliance" consideration that laws and regulations constitute the "floor" and not the "ceiling" of expected conduct. In other words, laws and regulations establish the bare minimum requirements that companies must abide by, but good companies, especially those that understand the

[5] *See, e.g.* Brent Saunders, Our Social Contract with Patients, Allergan CEO Blog (Sep. 6, 2016), https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients.aspx. Brent Saunders, current CEO of Allergan Plc and a former Compliance Officer for Schering-Plough Corporation wrote "[t]he health care industry has had a long-standing unwritten social contract with patients, physicians, policy makers and the public at large."

value of compliance, can and often do go farther.

The specific governing standards for what constitute effective compliance programs for the pharmaceutical industry are derived largely from four source categories. These are (1) state and federal statutes, plus any accompanying regulations, (2) government guidance documents, (3) industry enforcement settlements, and (4) voluntary industry standards including codes of conduct or ethics. Compliance professionals use these categories to develop compliance programs in the pharmaceutical industry that manage legal, regulatory and reputational risks effectively.

Finally, it is important to keep in mind that the origins of both controlled substances and corporate compliance programs predate the start of the report's review period (i.e., 1996).

## 3.2 The Interlocking Relationship between Suspicious Order Monitoring, Controlled Substances, and Corporate Compliance Programs

A suspicious order monitoring or SOM program is a subset of the wider universe of controls necessary for a distributor to meet its overall obligation to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[6] As discussed in greater detail below, that wider universe of controlled substances diversion controls is itself a subset of the universe of controls a distributor needs to meet its ability to exercise due diligence to prevent and detect inappropriate and potentially criminal conduct and to promote otherwise an organizational culture that encourages ethical conduct (a.k.a. a corporate compliance program). The figure below illustrates that the relationship between SOM, a full controlled substances program and the enterprise-wide corporate compliance program resembles a set of Russian nesting dolls.

[6] *See* 21 U.S.C. §§ 823 (b)(1). The Uniform Controlled Substances Act of 1994 states that "'diversion' means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use." *See* National Conference of Commissioners on Uniform State Laws, *Uniform Controlled Substances Act (1994)*, § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

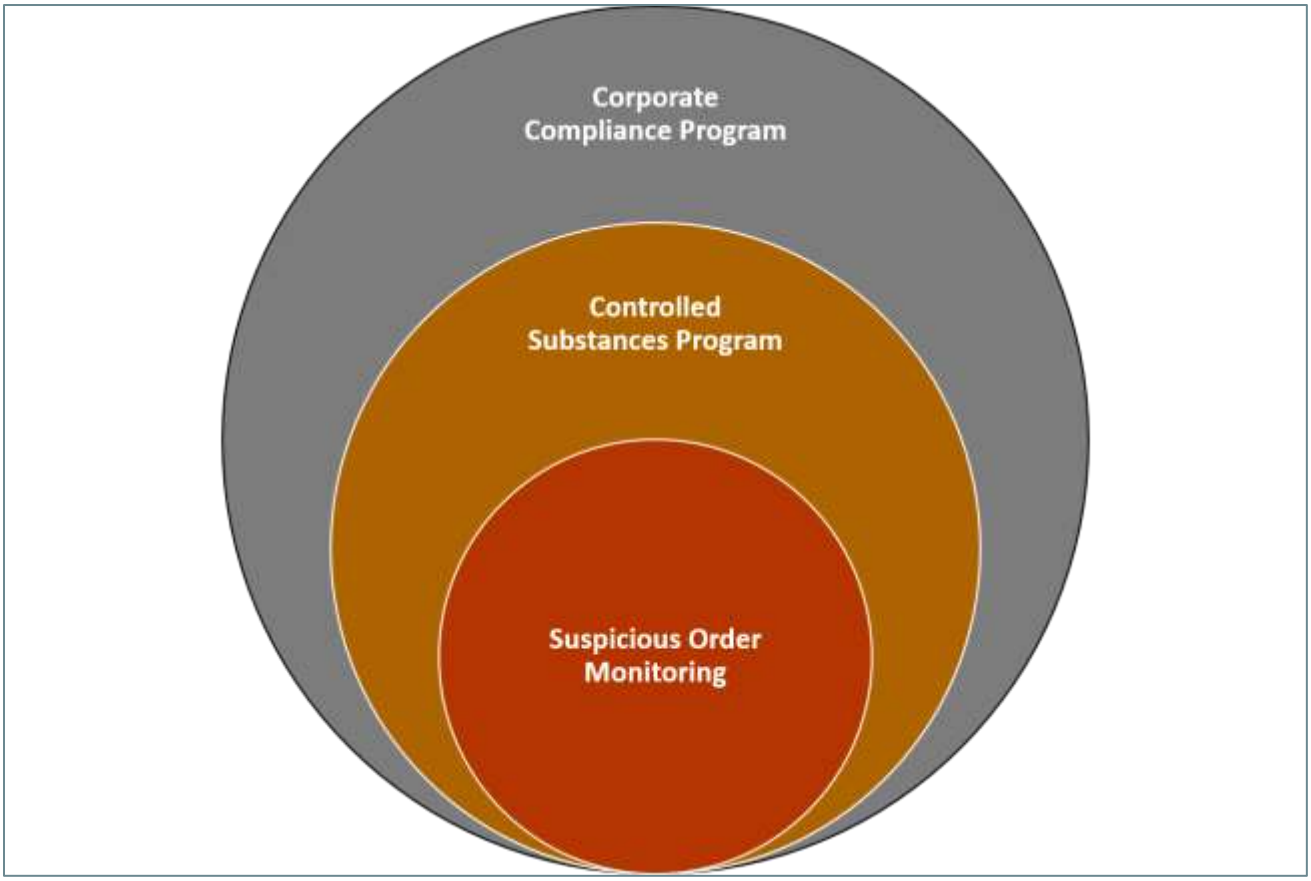


**Figure 1: Relationship Between SOM, Controlled Substances & Corporate Compliance**

As a result of this interlocking or "nested" arrangement, for a compliance program at any of the levels to be considered effective its basic building blocks must address the Seven, now Eight, Elements of an Effective Compliance Program.

# 4 Compliance Standards for Corporate Compliance Programs (1991 to the Present)

## 4.1 Federal Sentencing Guidelines for Organizations

In 1991, twenty years after passage of the CSA, the modern corporate compliance program was born with the publication of the first version of the Federal Sentencing Guidelines for Organizations ("FSGs"). Established by the U.S. Sentencing Commission ("Sentencing Commission"), the Guidelines are a "mechanical structure [that] determines an appropriate monetary fine through means of a mathematical formula: assigning a dollar figure to the seriousness of the offense and multiplying that number by a figure representing the culpability level of the

organization."[7] Consequently, "[t]he Guidelines' drafters intend[ed] to influence corporate behavior – both before and after wrongdoing occurs – by providing various adjustments to the determination of the seriousness of the offense and of the organization's culpability."[8]

Applying a "carrot and stick approach," the Sentencing Commission gave organizations an incentive to implement an effective compliance program. Therefore, the FSGs:

> not only encourage corporations to exemplify "good corporate citizenship," but [they] also provide a means to "rehabilitate' corporations that have engaged in criminal conduct ….[9]

According to the FSGs, "[t]he hallmark of an effective [compliance] program to prevent and detect violations of law is that the organization exercises due diligence in seeking to prevent and detect criminal conduct by its employees and other agents."[10] The Sentencing Commission, in a comment to the applications section, outlined seven criteria for establishing an effective compliance program. Commonly referred to as the "Seven Elements," the FSGs required that for a compliance program to qualify as "effective" and receive mitigation credits:[11]

1. The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct;
2. Specific individual(s) within the high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures;
3. The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew or should have known through the exercise of due diligence, had a propensity to engage in illegal activities;
4. The organization must have taken steps to communicate its standards and procedures effectively to all employees and other agents, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required;
5. The organization must have taken reasonable steps to achieve compliance with its standards, by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution;

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[7] *See* Lawrence Finder and A. Michael Warnecke, *Overview of The Federal Sentencing Guidelines for Organizations and corporate Compliance Programs*, 1, ABA Criminal Justice Section (Apr. 12, 2005) at https://www.americanbar.org/content/dam/aba/publishing/criminal_justice_section_newsletter/crimjust_wcc_OVERVIEW_OF_THE_FEDERAL_SENTENCING_GUIDELINES_FOR_ORGANIZATIONS_AND_CORPORATE.authcheckdam.pdf.

[8] *Id.*

[9] *See* Diane Murphy, *The Federal Sentencing Guidelines for Organizations: A Decade of Promoting Compliance and Ethics*, 87 IOWA L. REV. 697, 703 (2002) (citations omitted)

[10] *See id.* (Quoting from the U.S. Sentencing Guidelines Manual at ch. 8).

[11] *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

6. The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, the discipline of individuals responsible for the failure to detect an offense. The adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case specific; and

7. After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law.

These general elements outlined in the Sentencing Guidelines are not pharmaceutical-specific but rather apply to corporations across all industries. As the Sentencing Commission noted in its commentary, "[t]he precise actions necessary for an effective program to prevent and detect violations of law will depend upon a number of factors" including, but not limited to the size of the organization, the fact that via the nature of the business certain types of offenses are more likely to occur, and the organization's prior history.[12] Therefore, it is incumbent upon each corporation to implement the elements in a way that effectively addresses and mitigates the risks in their specific industry and for their individual company.

From their origin in 1991 through 2010, the Seven Elements were not legally or regulatorily mandated. Nevertheless, after the case of *U.S. v. C.R. Bard, Inc.* in 1994,[13] many of the larger pharmaceutical companies and other health care organizations began voluntarily implementing the Seven Elements with an understanding that the elements established the foundation for determining the worthiness of their compliance efforts and programs.

During this initial phase, the focus of industry activity and government enforcement actions was largely confined to establishing the role of the compliance officer and instituting the basic compliance framework outlined by the Federal Sentencing Guidelines.[14] The baseline requirements of a compliance program in this era typically involved:

1. Hiring a compliance officer and establishing a compliance committee;
2. Developing written compliance standards and policies;
3. Implementing an employee training program;
4. Establishing a confidential disclosure program (e.g., hotline);
5. Restricting the employment of ineligible persons (e.g., pre-employment screening); and
6. For companies under a plea agreement, providing implementation and annual reports to OIG on the status of the entity's compliance activities.[15]

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[12] *See id.*

[13] 848 F. Supp. 287 (D. Mass. 1994).

[14] *Id.* Although *Bard* was an FDA enforcement action against a medical device company, the settlement, which required the company to develop and implement a compliance program, helped motivate the pharmaceutical industry to make corporate compliance a priority.

[15] These baseline requirements were later expanded in 2001 with the TAP Pharmaceuticals Corporate Integrity Agreement. *See generally*, Corporate Integrity Agreement between DHHS OIG and TAP Pharmaceutical Products, Inc., https://www.oig hhs.gov/fraud/cia/agreements/tap_pharmaceutical_products_92801.pdf (2001). The TAP CIA saw the introduction of the Compliance Committee and the independent review organization ("IRO") to conduct annual reviews, as well as the

In 2004, the Federal Sentencing Commission significantly updated the Sentencing Guidelines. The corporate compliance program section was improved and expanded clearly signaling the importance of corporate compliance programs. Perhaps most importantly, the Sentencing Commission elevated the corporate compliance discussion from a comment to its own new chapter and section.[16] The Commission also made three other major changes.

First, with the addition of "ethics" to the program name, the Sentencing Commission signaled that these programs have an expanded role beyond just detecting and preventing criminal conduct. As of 2004, an effective ethics and compliance program was intended to promote "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[17]

Second, the Seven Elements were expanded to include an eighth element – risk assessment. Although listed explicitly for the first time, the risk assessment element was implied in the original 1991 Guidelines comment.[18] With the 2004 changes, the section explicitly highlighted it stating:

> In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.[19]

Third, the Sentencing Commission explicitly articulated that courts and judges could apply industry practice and standards in government regulations when concluding whether a compliance program was effective, and the failure to take governmental guidance and industry standards into account was viewed as a negative.

Specifically, the Commission wrote:

> (A) **In General.**—Each of the requirements set forth in this guideline shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, factors that shall be considered include: (i) applicable industry practice or the standards called for by any applicable governmental regulation; (ii) the size of the organization; and (iii) similar misconduct.
>
> (B) **Applicable Governmental Regulation and Industry Practice.** —An organization's failure

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requirement to make self-disclosures to the OIG of overpayments, investigations, legal proceedings, and other "reportable events" defined by the agreement. That settlement also introduced the conjoined concepts of the "covered person" and "certain covered persons" targeting various groups of employees for additional scrutiny and training. Now, instead of just one class of employees requiring training, the TAP CIA, and its progeny, required companies to identify those employees who constituted "covered persons or "certain covered persons" and establish and track training programs, as well as certifications, tailored specifically to each group.

[16] *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8B.2.1 (Nov. 2004) ["FSGs 2004"]. Section 8B.2.1 was amended in 2010, 2011 and 2013, however, those amendments were technical in nature and did not affect the overall requirements set out in that section. *See* U.S. Sentencing Commission, *Guidelines Manual*, Appendix C and Supplement to Appendix C (Nov. 2018) (Amendments 744, 758 and 778). Therefore, the 2004 Sentencing Guidelines contain the last major substantive update to the compliance program section.

[17] *See id.* at § 8B.2.1(a)(2).

[18] Although this concept was noted in the 1991 version, it was the very last sentence of the comment. *See* U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991).

[19] *Id.* at § 8B.2.1(c).

> to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.[20]

## 4.2 OIG Compliance Program Guidance

From 1998 to 2008, the Office of Inspector General ("OIG") for Health and Human Services issued a series of compliance program guidance documents that pertained to a wide variety of healthcare organizations and companies including hospitals, home health agencies and clinical laboratories in 1998[21], durable medical equipment, and hospices in 1999[22], pharmaceutical manufacturers in 2003[23] and nursing facilities in 2008.[24] According to the OIG, '[t]he purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements."[25] Each guidance followed a standard pattern of discussing the elements of an effective compliance program, as articulated by the Sentencing Guidelines, in the context of that particular industry segment. The compliance program guidance also represented the OIG's position on what constituted leading practices at that time for that industry segment.

Although the OIG never established specific compliance program guidance for pharmaceutical distributors, a close reading of the guidance published in 2003 for pharmaceutical manufacturers provides many informative insights suitable for distributors as well. In fact, the OIG noted that the information contained in the Guidance might be useful to other groups beyond just pharmaceutical manufacturers:

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[20] *See* FSGs 2004. at § 8B.2.1, comment. (n. 2) (emphasis added). In 2005, the U.S. Supreme Court in a complex opinion concluded that the Sentencing Guidelines violated a defendant's Sixth Amendment right to a jury, but also found that courts could still use them, provided the court was able to tailor the final sentencing to address the specific facts of the case. *See* Finder at 2 (Discussing *United States v. Booker*, 123 S. Ct. 785 (2005)). The DOJ in response issued a memorandum to all federal prosecutors instructing them that they are required to use the Sentencing Guidelines and ranges in all but the extraordinary case. *See* Memorandum from James B. Comey, Dep. Atty. Gen. To All Fed. Prosecutors, *Department Policies and Procedures Concerning Sentencing* (Jan. 28, 2005), available at http://sentencing.typepad.com/sentencing_law_and_policy/files/dag_jan_28_comey_memo_on_booker.pdf. The net result is that despite *Booker's* holding, the Sentencing Guidelines continue to define the elements of an effective ethics and compliance program by the courts, the regulators and the life sciences industry, and the passage of the Affordable Care Act in 2010 (see below) has eroded *Booker*'s relevance even further.

[21] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998); OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410 (Aug. 7, 1998); OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (Aug. 24, 1998). All OIG Compliance Guidance documents are available at https://www.oig hhs.gov/compliance/compliance-guidance/index.asp. To date, the OIG has published no specific compliance program guidance document for distributors.

[22] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry, 64 Fed. Reg. 36368 (Jul. 6, 1999); OIG Compliance Program Guidance for Hospices, 64 Fed. Reg. 54031 (Oct. 5, 1999).

[23] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Pharma Guidance").

[24] *See* Department of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42410 (Aug. 7, 1998).

[25] *See* OIG Pharma Guidance at 23731.

> In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs.[26]

As experienced compliance professionals know, any compliance program guidance does not necessarily need to be written for the specific industry segment to contain pertinent insights on what constitutes effective compliance.

## 4.3 Affordable Care Act

Perhaps the most significant change for corporate compliance programs occurred with the passage of the Affordable Care Act ("ACA") in 2010.[27] As noted previously, the standards detailing what constitutes the make-up of an effective compliance program have existed since 1991 and were widely adopted by most large pharmaceutical manufacturers and other prudent life sciences companies. They also were incorporated in various government guidance documents and settlement agreements. However, the passage of the ACA now made having a corporate compliance program a requirement to be eligible to participate in and receive reimbursement from federal health care programs.

Under ACA section 6401(a)(7) in order to participate in the Medicare program (e.g., receive reimbursement) after an implementation date determined by the Secretary of HHS:

> a provider of medical or other ***items or services or supplier*** within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.[28]

The same requirement also was applied to participants in state Medicaid programs, as well as the Children's Health Insurance Program ("CHIP").[29]

Congress used the concept of "core elements" to tie the previous corporate compliance guidance and standards into this new requirement by stating:

> The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.[30]

Congress also was specific regarding the Secretary's implementation determination that:

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[26] *See* OIG Pharma Guidance at 23742, n.5.

[27] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6401(a)(7), 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010) [hereinafter cited as ACA]

[28] *Id.* at § 6401(a)(7)(A) (Emphasis added).

[29] *Id.* at § 6401(b)(5) and (c)(2).

[30] *Id.* at § 6401(a)(7)(B).

> The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. **The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.**[31]

### 4.4 DOJ & OIG Program Effectiveness Guidance

In 2017, both the OIG and DOJ published guidance on the elements that they consider when determining whether a corporate compliance program is effective.[32] However, "[b]oth sets of guidance emphasize that they are not a 'checklist to be applied wholesale to assess a compliance program' but rather are lists of common elements to be considered when "making an individualized determination."[33] In addition, while there are similarities between the two guidance documents, there also some significant differences starting with the format. The DOJ guidance is formulated as questions to be considered, while the OIG document examines things to measure and how to accomplish those measurements.

## 5 Compliance Standards for Controlled Substances (1970 – the Present)

### 5.1 Controlled Substances Act

The origins of effective compliance programs for controlled substances (a.k.a. anti-diversion programs) are traceable to the enactment of both the Controlled Substances Act ("CSA"), which is the primary statute governing the manufacture and distribution of controlled substances, and the Drug Enforcement Administration's ("DEA") implementing regulations.[34] Originally enacted in 1970, the CSA established the classification system for controlled substances (Schedules I-V), as well as general controls that pertain to each

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[31] *Id.* at § 6401(a)(7)(C) (Emphasis added). As of the date of this report, the Secretary has not issued a formal determination of "core elements" under subparagraph (B) or the implementation date under subparagraph (C). However, given the existence of the Federal Sentencing Guidelines, the OIG Compliance Program Guidance in 2003 and the most recent OIG and DOJ guidance documents on program effectiveness issued in 2017, I believe the pragmatic compliance reading is that the "core elements" and timing requirements have been satisfied. Consequently, as of 2010, any pharmaceutical distributor, which receives federal healthcare dollars either directly or indirectly, must have an effective corporate compliance program that addresses the risks in a particular industry or industry category.

[32] *See* U.S. Department of Justice, Criminal Division- Fraud Section, "Evaluation of Corporate Compliance Programs," https://www.justice.gov/criminal-fraud/page/file/937501/download; *see also* HCCA-OIG Compliance Effectiveness Roundtable, Measuring *Compliance Program Effectiveness: A Resource Guide* (Mar. 27, 2017) ("On January 17, 2017 a group of compliance professionals and staff from the Department of Health and Human Services, Office of Inspector General (OIG) met to discuss ways to measure effectiveness of compliance programs."), available at https://oig hhs. gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf.

[33] *See* S. Foroughi and K. Wildoner, *Effectiveness, The Holy Grail of Compliance - Both the DOJ & OIG Weigh In*, 3.7 LIFE SCIENCE COMPLIANCE UPDATE 7, 14 (Jul. 2017) (citations omitted), available at https://complianceupdate.policymed.com.

[34] *See* 21 U.S.C. § 801 *et seq., see also* 36 Fed. Reg. 7778 (Apr. 24, 1971) codified at 21 C.F.R. part 1301.

schedule.[35] Regardless of the Schedule level, the fact that a medicinal product is scheduled means that it has been determined that additional controls regarding the manufacture, distribution, dispensing and prescribing of that product are necessary to safe guard the public health.[36]

Schedule II products are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.[37] Consequently, products in this category are considered the most dangerous products that can be lawfully prescribed by a medical professional. Schedule III products are defined as drugs with a potential for abuse that is less than the drugs in Schedules I and II, with use potentially leading to moderate to low physical dependence and high psychological dependence.[38] While these products are considered less dangerous than Schedule II drugs, nevertheless, they are potent medicinal products requiring the additional controls mandated by the CSA to prevent diversion and misuse.

As a baseline, the CSA requires that all major participants in the controlled substance supply chain (manufacturers, distributors, dispensers, and prescribers) be registered, thus creating the so-called "closed loop" system.[39] It further defines the basic controls expected of both manufacturers and distributors. A critical condition for granting, and maintaining, a manufacturer's or distributor's registration is the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[40] The failure of any registrant to "refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required" by the Act is a criminal offense.[41]

Although the CSA has been amended several times since 1970, this basic requirement to maintain effective diversion controls has remained untouched.[42] Therefore, when the manufacturers and distributors developed the governing standards of conduct to detect and prevent diversion of prescription opioids, it was incumbent on

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[35] *See* 21 U.S.C. §§ 812(b)(2), (b)(3) and (c). The CSA defines an opioid as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." *See* 21 U.S.C. § 802(18). For purposes of this review the focus is opioid products, which are classified as Schedule II or III controlled substances.

[36] *See, e.g.*, U.S. DEPARTMENT OF JUSTICE, DRUG ENFORCEMENT AGENCY, 96-2 DIVERSION INVESTIGATOR'S MANUAL, § 5126 (Apr. 16, 1996), CAH_MDL_02203357.

[37] *See* 21 U.S.C. § 812(b)(2).

[38] *See* 21 U.S.C. § 812(b)(3).

[39] *See* 21 U.S.C. § 823.

[40] *See* 21 U.S.C. §§ 823 (a)(1) and (b)(1) (Governing manufacturers and distributors respectively). As a threshold matter, the CSA does not specifically define "diversion." However, the language "into other than legitimate medical, scientific, and industrial channels" infers that if a controlled substance were moved into an illegitimate channel that constitutes "diversion." According to the Uniform Controlled Substances of 1994, "'diversion' means the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use." *See* National Conference Of Commissioners on Uniform State Laws**,** *Uniform Controlled Substances Act (1994*), § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

[41] *See* 21 U.S.C. § 842(a)(5).

[42] *See, e.g.*, Pub. L. 91-513 available at https://www.gpo.gov/fdsys/pkg/STATUTE-84/pdf/STATUTE-84-Pg1236.pdf (Comprehensive Drug Abuse Prevention and Control Act of 1970).

each of them to consider the CSA's requirements as they developed and maintained an effective anti-diversion program.

## 5.2 DEA Controlled Substances Regulations

A year after passage of the CSA, the DEA in 1971 issued implementing regulations to clarify many of the CSA's important provisions including the registration and security controls for manufacturers, distributors, and dispensers of controlled substances.[43] A crucial component for controlled substances distributors was the security controls section outlining the physical security and other controls for non-practitioners.[44]

Building from the original CSA provisions, the DEA's regulations required that all non-practitioner registrants (e.g., manufactures and distributors) develop and maintain:

> effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.[45]

The types of security controls that manufacturers and distributors must employ include:[46]

- Making a good faith inquiry to determine if the person or entity receiving controlled substances is authorized to receive them;
- Maintaining a system to detect and disclose suspicious orders (a.k.a. Suspicious Order Monitoring or SOM);
- Notifying the DEA of thefts or significant losses; and
- Ensuring that any common carriers used in the supply chain have adequate security measures to prevent losses.

As laid out by the DEA regulations, a manufacturer's and distributor's SOM program must meet a relatively short list of requirements:

- There must be a system designed and operated to disclose suspicious orders of controlled substances.
- The distributor must inform the local DEA Field Office when the distributor discovers a suspicious order.
- At a minimum, orders are deemed suspicious if they are (a) of unusual size, (b) deviate substantially from a normal pattern, or (c) of unusual frequency.[47]

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[43] *See* 36 Fed. Reg. 7778 (Apr. 24, 1971) codified at 21 C.F.R. part 1301.

[44] *See* 21 C.F.R. §§ 1301.72 and 1301.74.

[45] *Id.* at § 1301.71(a).

[46] *See id.* at 1301.74.

[47] *See* 21 C.F.R. § 1301.74(b); *see also Masters Pharmaceuticals, Inc. v. DEA*, 15-1335 (D.C. Cir. 2017) (upholding DEA's interpretations of its regulations relative to defining a suspicious order and the timing of reporting).

Additionally, any manufacturer, which provides complimentary samples, must maintain appropriate controls for controlled substances in addition to the general controls for pharmaceutical marketing samples.[48]

Also embedded within the DEA's regulations was the important concept that effective security controls are not static.[49] The regulations expressly contemplated that security controls should be adjusted (increased or decreased) to account for changing circumstances.[50] When determining whether a registrant is in substantial compliance with the security requirements, the DEA may apply a variety of factors, including but not limited to, "[t]he adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations."[51] Therefore, as of 1971, both manufacturers and distributors were on notice that, at a minimum, they were expected to assess their controls periodically (e.g., undertake a risk assessment), as well as maintain a system to detect suspicious orders of controlled substances.

## 5.3 DEA Guidance on Controlled Substances

### 5.3.1 Controlled Substances Security Manual & Suspicious Order Task Force (1997 to 2004)

In 1991, the DEA published the Controlled Substances Security Manual as an informational guide to the CSA.[52] The manual provided a more user-friendly outline of the CSA and its accompanying regulations. Later, in November 1997, the DEA announced the formation of the Suspicious Order Task Force.[53] The task force was "responsible for providing the Attorney General with recommendations, advice, and proposals for the establishment of such guidelines that will adequately define suspicious orders of listed chemicals."[54] It was comprised of 20 members including members from "relevant industry/trade associations and state and local law enforcement agencies."[55]

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[48] *Id.* The PDMA, which is administered by the U.S. Food and Drug Administration ("FDA") governs the distribution of pharmaceutical marketing samples. FDA's regulations for the most part mirror the DEA's requiring proof of to whom the samples were delivered, reporting of significant losses, investigating losses and suspected falsification, and providing timely notification of losses to the Agency. *See* 21 C.F.R. part 203. One difference between the two regulatory schemes is that the FDA specifically mandates the manufacturer maintain written policies and procedures governing how its sample accountability systems and processes operate. *See* 21 C.F.R. § 203.34. In 2010, the ACA added section 6004 which added yet another layer to the sampling of non-scheduled pharmaceuticals moving them closer to the "closed loop" DEA system. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6004, 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G) (2010).

[49] *See, e.g.*, Letter from W. Goggin to J.M. Gray (Oct. 17, 2008) ("diversion control is not a 'one size fits all' effort), WAGMDL00673706.

[50] *Id.* at § 1301.71(c).

[51] *Id.* at § 1301.71(b)(14).

[52] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION, CONTROLLED SUBSTANCES SECURITY MANUAL (May 1991) available at http://www.cogan.com/documents/DEA_Controlled_Substances_Security_Manual.pdf.

[53] *See* 62 Fed. Reg. 61829 (Nov. 19, 1997).

[54] *Id.*

[55] *Id.*

### 5.3.2 The Chemical Handler's Manual

The DEA created the Chemical Handler's Manual in response to the enactment of the various chemical control laws, amending the original CSA, but also to provide general guidance on complying with the CSA.[56] Therefore, it contains relevant guidance on diversion controls and suspicious orders, including suspicious order identification criteria established by the Task Force.[57]

The Manual also outlined "a voluntary formula for use by distributors to wholesale and retail levels."[58] The formula outlined involved setting threshold purchase levels based on the last twelve months purchases by the same customer type from the same distribution center (e.g., the customer group).[59] That amount is divided by the total number of customer months (months in which purchases are above zero) and multiplied by a factor to determine the maximum amount a customer may purchase.[60] According to the Manual, the "[f]actor equals 3 for C-II and C-III Controlled Substances **containing List I Chemicals** and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products **containing List I chemical items**."[61]

While the manufacturers and distributors here utilized the Factor of 3 for setting thresholds for opioid products, the factor was based only on Schedule II and III controlled substances containing List 1 Chemicals.[62] A plain reading of Appendix E-3 is that if a Schedule II or III controlled substance does not contain a List 1 chemical, the factor is not applicable. Therefore, for opioid products not containing a List 1 chemical, that factor is not applicable. However, regardless of whether using the factor is applicable or not, the DEA manual does not indicate how a level that is 300% above the base threshold is the appropriate multiplier to use.

Independent of the type of products the Chemical Handler's Manual applies to, it is clear that the Manual does not support the practice of shipping suspicious orders after they are reported. To this point, the Chemical Handler's Manual states "when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions."[63]

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[56] *See* U.S. DEP'T OF JUSTICE, DRUG ENFORCEMENT ADMINISTRATION CHEMICAL HANDLER'S MANUAL, (Jan. 2004) at https://www.justice.gov/sites/default/files/open/legacy/2014/05/09/2004-chemical-handlers-manual.pdf. ["Chemical Handlers Manual, 2004 Edition"].

[57] *Id.* at 37 (Appendix E).

[58] *Id.* at 41 (Appendix E-3).

[59] *Id.*

[60] *Id.*

[61] *Id.* (emphasis added).

[62] The Manual states that a "*List I chemical* is a chemical that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a List I chemical by the DEA Administrator or Congress. Chemicals in List I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals." *See id.* at 8 (emphasis added).

[63] *See* Chemical Handler's Manual, 2004 Edition, at 19.

### 5.3.3 The DEA Industry Initiative

"Recognizing that wholesale distributors played a key role in the pharmaceutical supply chain, the DEA launched an industry-specific anti-diversion initiative in 2005, called the "'Distributor Initiative Program.'"[64] According to the DEA, the goal of the initiative was to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."[65] Initially, the DEA focused the program on educating drug distributors who were supplying controlled substances to rogue Internet pharmacies and to diverting pain clinics and pharmacies.[66] Through the program, the DEA "educates distributors about their obligations under the CSA, as well as provides registrants with current trends and 'red flags' that might indicate that an order is suspicious."[67] McKesson, Cardinal Health, and Amerisource Bergen all attended sessions with the DEA.[68] The materials used in each meeting were almost identical.[69]

During those meetings, the DEA told the participants that:

1. Reporting a suspicious order to the DEA does not relieve the distributor of its responsibility to maintain effective anti-diversion controls.
2. The DEA cannot tell distributors if an order is legitimate or not.
3. Distributors, therefore, must determine which orders are suspicious and decide whether to proceed with the sale.
4. If distributors know or suspect that controlled substances are being dispensed outside the course of professional practice shipments to those customers must stop immediately.
5. The DEA may revoke a distributor's registration under public interest grounds.[70]

Although couched in terms of distributors, because the requirements for manufacturers are the same, the DEA's statements as part of this initiative would apply to them too.

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[64] *See* MEMORANDUM FROM COMMITTEE MAJORITY STAFF, H.R. COMM. ON ENERGY AND COMMERCE, SUBCMTE. ON OVERSIGHT AND INVESTIGATIONS, HEARING ENTITLED "COMBATING THE OPIOID EPIDEMIC: EXAMINING CONCERNS ABOUT DISTRIBUTION AND DIVERSION," 5, (May 4, 2018), https://docs.house.gov/meetings/IF/IF02/20180508/108260/HHRG-115-IF02-20180508-SD002.pdf.

[65] *Id.* (quoting from *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.)).

[66] *See id.*

[67] *See id.* (quoting from *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin.)).

[68] *See* Memorandum to J. Rannazzisi from M. Mapes, Internet Presentation with McKesson Corp. on September 1, 2005 (Oct. 20, 2005), MCKMDL00496859; Presentation by M. Mapes and K. Wright to Cardinal Health, *Internet Pharmacy Data*, (Aug. 22, 2005), CAH_MDL2804_01457737; Presentation by M. Mapes and K. Wright to AmerisourceBergen, *Internet Pharmacy Data*, (Aug. 10, 2005), ABDCMDL00315887.

[69] *Id.*

[70] *See* Presentation by Mapes and Wright to AmerisourceBergen at ABDCMDL00315893-94, and ABDCMDL00315899.

### 5.3.4 DEA Letters to All Registrants (a.k.a. The Rannazzisi Letters) (2006 to 2012)

In 2006, 2007 and again in 2012, Joseph Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control also issued a series of guidance letters.[71] Known collectively as the Rannazzisi letters, they were sent to all registered manufacturers and distributors reminding them of their obligations under the CSA to prevent diversion and detect suspicious orders.[72] Beyond the general reminders and disclaimer that the DEA does not endorse a particular system or sets of controls, each letter focused on a particular implementation topic, providing DEA's current thinking about what was or was not effective.

The initial letter in September 2006 focused on a registrant's basic obligations noting that the suspicious order monitoring "requirement is in addition to, and not in lieu of, the general requirement . . . that a distributor maintains effective controls against diversion."[73] The DEA also provided a list of factors that could signal possible diversion.[74]

The focus of the February and December 2007 letters again was suspicious order monitoring. While the February 2007 letter's content was almost identical to the September 2006 letter, the December 2007 letter focused on what constituted timely reporting.[75] The December letter also cautioned registrants about placing too much reliance on rigid formulas to detect diversion, as well as the need to conduct meaningful investigations of suspicious orders.[76]

The June 2012 letter continued the discussions started in December 2007 and once more focused on suspicious order monitoring. This time the DEA expressed concerns over registrants' not making timely reports to the DEA Field Offices as the regulations require. However, the DEA commented that merely reporting suspicious orders was not enough noting:

> Registrants who routinely report suspicious orders yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion.[77]

Thus, the DEA reiterated its expectation that registrants needed to conduct meaningful due diligence before

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[71] *See* Letters from J. Rannazzisi to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007 and Jun. 12, 2012) ["DEA (date) Letter(s)"].

[72] *Id.*

[73] *See* DEA 9/27/2006 Letter at 2.

[74] *See Id.* at 3 (Listing circumstances that might be indicative of diversion).

[75] *See* DEA 12/27/2007 Letter; *see also* Letter from G.Thomas Gitchel to R.J. Streck (Apr. 27, 1984) ("any automated data processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler."), CAH_MDL2804_01465723. Mr. Gitchel was the DEA's Acting Chief of the Diversion Operations Section at that time.

[76] *Id.*

[77] *See* DEA 6/12/2012 Letter at 2; *see also* HDMA *Position Statement and Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances* (2008), WAGMDL00673706-WAGMDL00673722.

shipping potentially suspicious orders.[78]

### 5.3.5 Masters Pharmaceutical Case

While the case revoking the DEA registration for Masters Pharmaceuticals, Inc. ultimately came before the D.C. Circuit,[79] the opinion of DEA's Acting Administrator Chuck Rosenberg provides specific guidance on the determination of exactly when an order of unusual size, frequency or pattern "is discovered" as "suspicious."[80] This determination is particularly important because if a suspicious order "is discovered," the manufacturer or distributor should not ship the order to the customer.[81] Thus, as discussed throughout this report, distributors and manufacturers go to extraordinary lengths to avoid "discovering" a suspicious order.

The regulations do not expressly define what is meant by "when discovered," and as a result, manufacturers and distributors use various euphemisms, such as "orders of interest" or like terms not found in the regulation as an attempt to avoid triggering the reporting requirement. However, the general principles of statutory construction hold that words not defined by a statute or regulation should be given their "plain meaning" as derived from the dictionary.[82] Consequently, when a manual or automated threshold system "discloses" the excessive/suspicious order that constitutes "when discovered" triggering the reporting requirement.

According to Mr Rosenberg's opinion "[s]uspicion as to the existence of a circumstance (i.e., that a customer is engaged in diversion) is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists … [and] does not even rise to the level of probable cause."[83] Thus, he concluded that "an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order."[84]

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[78] *Id.* In same vein as Rannazzisi letters, James Arnold, Unit Chief, Regulatory Unit, DEA HQ, in June 2013, spoke about diversion controls at a conference for manufacturers, importers and exporters hosted by the DEA. *See* Presentation by James Arnold, *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conference, (Jun. 2013) available at https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/. While largely a recap of the statute and regulations, Mr. Arnold made several important points during his talk. First, he stressed that the responsibility for identify suspicious orders is the registrant's, but once identified as suspicious, the order must not be shipped. *Id.* at slide 41. Second, Mr. Arnold noted registrants must know their customers and have determined if there are any "red flags" to doing business with them. These "red flags" can include any number of factors including, but limited to, the customer's location, news reports, etc. *Id.* at slides 42 to 53.

[79] *See Masters Pharmaceutical, Inc. v. DEA*, No. 15-1335, (D.C. Cir. 2017). The D.C. Circuit's opinion is relevant because the Court affirmed the positions taken by Acting Administrator Rosenberg.

[80] *See* 80 Fed. Reg. 55418 (Sept. 15, 2015).

[81] *See* Letter from J. Rannazzisi to All Registrants (Jun. 12, 2012); *see also* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 11 (2008) (blocking "orders of interest"), WAGMDL00673706.

[82] *See, e.g., Morissette v. United States*, 342 U.S. 246, 263 (1952); *FDIC v. Meyer*, 510 U.S. 471, 476 (1994) (In the absence of a statutory definition, "we construe a statutory term in accordance with its ordinary or natural meaning."); *see also* LARRY M. EIG, CONG. RESEARCH SERVICE, 97-589, STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS, 5-8 (2014).

[83] *See* 80 Fed. Reg at 55478.

[84] *Id.*

With regards to the "when discovered" provision, Mr. Rosenberg concluded the provision is intended "'to prevent manufacturers and distributors from simply filing "daily, weekly, or monthly" suspicious order reports'" because "'periodic reports delay the reporting of suspicious orders … meaning that DEA cannot act quickly when necessary.'"[85] However, he concluded that the purpose of the language is "to impose a time period for 'informing' the Agency about a specific suspicious order."[86]

Consequently, when a manual or automated threshold system "discloses" the excessive/suspicious order that constitutes "when discovered" and triggers the reporting requirement. However, it is reasonable to permit a brief investigatory period to avoid the submission of reports that have been flagged by the system, but clearly are not suspicious as determined through verifiable and documented means. Therefore, based on the guidance provided by Acting Administrator Rosenberg's conclusions in the *Masters* case, it is my opinion that this investigatory period is less than a week. To permit a longer investigative period would only increase the likelihood that the DEA will be provided stale information if the order is ultimately reported as suspicious, which would run counter to the Agency's ability to properly investigate the order. It is also clear that the registrant must not ship the order until it is determined not to be suspicious and if the registrant cannot make a determination within the investigatory period, the order must be reported to the DEA and canceled.

## 5.4 Industry Guidance

In 1987, the National Wholesale Druggists' Association ("NWDA") developed, with input from the DEA, a suspicious order monitoring program.[87] The NWDA program or system provided, among other things, that "[s]ingle orders of unusual size or deviation must be reported [to the DEA] immediately ... [t]he submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting those single excessive or suspicious orders. DEA has interpreted 'orders' to mean **prior to shipment**."[88]

Building on the guidance provided by the DEA, Healthcare Distribution Management Association ("HDMA"), in 2008, developed voluntary industry guidelines to provide clear direction on how to develop a compliant anti-diversion program.[89] These general guidelines, which must be adapted by each individual distributor, cover the critical anti-diversion topics including:

- Know Your Customer Due Diligence;
- Monitoring for Suspicious Orders;

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[85] *Id.*

[86] *Id.*

[87] *See NWDA "Suspicious Drug Order" Monitoring Program*, THE PINK SHEET (May 11, 1987), https://pink.pharmaintelligence.informa.com/PS011879/NWDA-SUSPICIOUS-DRUG-ORDER-MONITORING-PROGRAM. The National Wholes Druggists' Association became the Healthcare Distribution Management Association ("HDMA") in 2000 and in 2016 HDMA became the Healthcare Distribution Alliance ("HDA"). *See* HDA, *History*, https://www.hda.org/about/hda-history (last accessed Feb. 21, 2019).

[88] *See* Nat'l Wholesale Druggists' Ass'n, NWDA Suspicious Order Monitoring System, 7 (Jun. 21, 1993) (emphasis added), CAH_MDL2804_01465723.

[89] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 13 (2008), WAGMDL00673706.

- Suspend/Stop an Order of Interest Shipment;
- Investigation of Orders of Interest;
- File Suspicious Order Reports with DEA;
- Employees, Training and Standard Operating Procedures; and
- Additional Recommendations.[90]

While the Compliance Guidelines incorporate the provisions found in the CSA, the DEA regulations, and the various guidance documents from DEA, they also add concepts not found in those documents. For example, it is in the HDMA guidelines that the term "orders of interest" appears. As defined by HDMA, "orders of interest" are "orders that warrant follow-up inquiry to determine whether they are suspicious."[91] Furthermore, it appears that the letter from Wendy Goggin, Chief Counsel for DEA, commending HDMA's efforts, is where the industry gets the mistaken belief that DEA "endorsed" the Compliance Guidelines, including the "orders of interest" concept.[92] Also, HDMA in the Industry Compliance Guidelines counseled, "[d]istributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report 'when discovered.'"[93]

[90] *Id.* at 3.

[91] *Id.* at 8.

[92] *See*, Letter from W. Goggin to J.M. Gray (Oct. 17, 2008) ("diversion control is not a 'one size fits all' effort), WAGMDL00673706.

[93] *See* HDMA, Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, 13 (2008) (emphasis added), WAGMDL00673706.

# PART III: Defining What Good Looks Like

## 6 Applying the Standards

As discussed in Part II, by the mid-1990s, the concept of "what good looks like" was established both in the context of corporate and controlled substances (a.k.a. anti-diversion) compliance. From that point forward it was clear that companies in the pharmaceutical industry, including manufacturers and distributors of opioid products, could develop effective internal controls to achieve the objectives to prevent and detect criminal conduct by an organization's employees and agents working on behalf of the organization and to guard against theft and diversion of controlled substances.[94]

In the U.S., the basic regulatory construct for pharmaceuticals, regardless of the agency, is to provide the industry with "what" is expected, but not dictate "how" those expectations are achieved. The "how" is left to the individual organizations to determine the best methods to comply. This approach is true in the case of the OIG, DEA, and even the FDA.[95]

[94] *See* Appendix B, Figures 2 and 3 for diagrams outlining a controlled substances compliance program (a.k.a. anti-diversion program) and a corporate compliance program.

[95] *See, e.g.*, U.S. Sentencing Commission, *Guidelines Manual*, § 8A.1.2, comment. (n. 3k) (Nov. 1991) ["FSGs 1991"]; J. Rannazzisi letters to All Registrants (Sep. 27, 2006, Feb. 7, 2007, Dec. 27, 2007 and Jun. 12, 2012) (These letters were not McKesson specific but sent to all DEA registrants), MCKMDL00478906, MCKMDL00615308, MCKMDL00478910, MCKMDL00449807 ["DEA (date) Letter"]; U.S. Food and Drug Admin., Center for Drug Evaluation and Research, *Facts About the Current Good Manufacturing Practices (CGMPs)*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105 htm, (page last updated Jun. 25, 2018) (last accessed Dec. 8, 2018) ("The CGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures.").

## 6.1 General Principles

### 6.1.1 Corporate Compliance Programs

For any compliance program to be considered effective its basic building blocks must address the Seven, now Eight Elements of an Effective Compliance Program. These elements, whether for enterprise-wide or for controlled substances, are:

1. Organization and Resources
2. Due Diligence
3. Written Standards
4. Training & Communication
5. Monitoring, Auditing & Investigations
6. Corrective Actions
7. Enforcement (i.e., Discipline or other consequences for violating the standards)
8. Periodic Risk Assessment

While the eight elements provide a generally accepted and cohesive framework to assess compliance effectiveness, there is overlap between them, and therefore separating specific compliance activities by element is something of an esoteric exercise.

For purposes of simplicity and consistency when looking holistically across the entities assessed in my report, I grouped the eight elements listed above as follows:

**Table 5.1-1 – Grouping the Eight Elements**

| Category | Elements of an Effective Compliance Program |
|---|---|
| **Company Commitment** | 1. Organization and Resources (including company culture) |
| **Program Core** | 3. Written Standards<br>4. Training & Communication<br>5. Monitoring, Auditing & Investigations<br>6. Corrective Actions<br>8. Periodic Risk Assessments |
| **Accountability** | 2. Due Diligence (i.e., avoiding bad actors)<br>7. Enforcement (i.e., Discipline or other consequences for violating the standards) |

Furthermore, although each type of compliance program has a specific focus (general enterprise-wide compliance versus controlled substances distribution compliance versus suspicious order monitoring), the

detailed standards applicable to all three types of compliance programs discussed here should be read together, as they reinforce and build-off each other.

Since the mid-1990's little has changed in the fundamentals in either the corporate compliance or controlled substances spheres, rather Main Justice, the DEA, and the OIG have become increasingly more pointed in reminding the pharmaceutical industry of what its statutory and regulatory obligations are with respect to corporate and controlled substances compliance. Even the introduction of new technology (e.g., ARCOS) has done little to change the fundamental compliance dynamic operating since 1995.

For example, in the context of monitoring compliance, technology arguably increases the amount of information that can be sorted, filtered and rapidly transmitted, but even today it merely provides an output of outliers and anomalies. Therefore, corporate and controlled substances compliance programs must still rely on experienced human resources, with intelligence and common sense, to review and understand the context surrounding each outlier or anomaly and then to apply the correct, balanced solution. Thus, in the end, good compliance comes down to experienced people making good choices.

It also comes down to the need for "objective evidence" to demonstrate that required compliance obligations including effectiveness, have been met. Thus, written documentation is the bedrock of demonstrating or "proving" that an organization's claims of effectiveness (or lack of thereof) are real. For example, as the Public Company Accounting Oversight Board ("PCAOB") points out in the context of audits:

> Inadequate audit documentation diminishes audit quality on many levels. First, if audit documentation does not exist for a particular procedure or conclusion related to a significant matter, its absence casts doubt as to whether the necessary work was done.[96]

The same applies to compliance efforts. Placing the PCAOB's comments about audit documentation into a compliance context:

> Inadequate **compliance** documentation diminishes **compliance** quality on many levels. First, if **compliance** documentation does not exist for a particular procedure or conclusion related to a significant matter, its absence casts doubt as to whether the necessary work was done.

This is the same point made by the House Energy and Commerce Committee report.[97]

Thus, if there is no documentation showing what is claimed was accomplished, the reasonable presumption is that it was not accomplished. Consequently, underlying all the applicable standards is the presumed need for good, written documentation to substantiate the existence and proper operation of compliance controls.

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[96] *See* PCAOB, *Audit Documentation and Amendment to Interim Auditing Standards*, PCAOB Release No. 2004-006 (Jun. 9, 2004) (Announcing adoption of Audit Standard No. 3 on audit documentation). Reference to the PCAOB is appropriate in this context because most of the distributors reviewed are publicly traded entities and thus must arrange for independent audits of their financial statements. For those entities that are privately-held, there remains a basic fiduciary duty to the owners and company directors that also necessitates good documentation exists.

[97] *See* WVA Red Flags Report at 124-125, 130 and 319 (repeatedly commenting on the lack of due diligence documentation by distributors).

### 6.1.2 Suspicious Order Monitoring Programs

Overall, a distributor's SOM program must meet a relatively short list of requirements:

1. There must be a system designed and operated to disclose suspicious orders of controlled substances.
2. The distributor must inform the local DEA Field Office when the distributor discovers a suspicious order.
3. At a minimum, orders are deemed suspicious if they are (a) of unusual size, (b) deviate substantially from a normal pattern, or (c) of unusual frequency.
4. Suspicious orders must be held and not shipped until it is determined that the order likely will not be diverted.[98]

As a threshold matter, the distributor or manufacturer must determine if the controlled substances customer is properly licensed to possess the controlled substance.[99] Both must also take steps to "know the customer," in other words, they need:

> to take reasonable measures to verify the identity of their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, detect those transactions that are suspicious in nature.[100]

As noted throughout this report, the "Know Your Customer" or KYC concept is critical to having a successful SOM program. To be effective, distributors and manufacturers must build and maintain profiles of their customers that are more specific than segregating those customers into various classes of trade. For example, knowing a pharmacy's product mix of controlled versus non-controlled prescriptions together with local data such as the number of residents, age as a percentage of residents, number and type of physicians and healthcare facilities, etc., are all important pieces of information that can make up a "Know Your Customer" profile. As the DEA makes clear, the Know Your Customer requirement is the basis for determining whether a customer's purchases are to be considered legitimate or diversionary. However, it also is important to remember that knowing one's customer and making determinations of whether orders are suspicious or legitimate is not simply a scientific endeavor (e.g., just using thresholds and algorithms), but also is an art requiring training, experience, innate skepticism, and common sense.

However, detecting and subsequently reporting suspicious orders are just a part of the overall set of controls a distributor and manufacturer needs to employ to prevent diversion. If "diversion" is taken to mean moving controlled substances into illegitimate "medical, scientific, [or] industrial channels"[101] or if it is taken to mean "the transfer of a controlled substance from a lawful to an unlawful channel of distribution or use,"[102] then to

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[98] *See* 21 C.F.R. § 1301.74(b); *see also Masters Pharmaceuticals, Inc. v. DEA*, 15-1335 (D.C. Cir. 2017) (upholding DEA's interpretations of its regulations relative to defining a suspicious order and the timing of reporting).

[99] *See* 21 C.F.R. § 1301.74(a).

[100] *See* U.S. Dep't. of Justice, Drug Enforcement Administration *Chemical Handler's Manual*, 21 (2013) at https://www.deadiversion.usdoj.gov/pubs/manuals/chem/chem_manual.pdf.

[101] *See* 21 U.S.C. §§ 823 (b)(1).

[102] *See* Nat'l Conf. of Commissioners on Uniform State Laws, *Uniform Controlled Substances Act (1994),* § 309(a) (Dec. 28, 1995) at http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf.

prevent potential diversion, one needs to ensure that suspicious orders are not shipped until an appropriate investigation concludes that the risks of diversion occurring are not present.[103]

Taking it one step further, since maintaining effective controls against diversion is just part of a manufacturer and distributor's overall responsibility to exercise due diligence to prevent and detect criminal conduct, the controlled substances program and suspicious order monitoring system need to have controls, including but not limited to, conducting periodic risk assessments and undertaking appropriate corrective actions that flow from the company's compliance standards. Otherwise, that distributor or manufacturer cannot contend that it has maintained effective controls against diversion or that its corporate compliance efforts are effective.

## 6.2 Compliance Culture, Organization & Resources

The 2004 Federal Sentencing Guidelines ("FSGs") mandate that for an ethics and compliance program to be considered effective, it must promote "an organizational culture that encourages ethical conduct and a commitment to compliance with the law."[104] As the OIG explained the year before in its 2003 Compliance Program Guidance, promoting and encouraging a commitment to ethics means:

> for a compliance program to be effective, it must have the **support and commitment of senior management** and the company's governing body. In turn, the corporate leadership should strive to **foster a culture** that promotes the prevention, detection, and resolution of instances of problems.[105]

For any compliance program to be successful, it must have adequate resources and the authority to achieve real compliance, and not just be delegated the responsibility for compliance.[106] In other words, responsibility without actual authority and appropriate resources is meaningless. Therefore, the culture of an organization, as well as the structure and resources are important elements of an effective compliance program.

Under the 2004 FSGs, in addition to requiring that high-level personnel in the organization be assigned responsibility for a compliance program, the Guidelines mandate:

- The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program [and]

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[103] *See* Letter from Wendy Goggin to John Gray (Oct. 17, 2008) (discussing HDMA's voluntary industry guidelines, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances.") WAGMDL00673706.

[104] *See* FSGs 2004 at § 8B.2.1(a)(2).

[105] *See* Dept. of Health and Human Services, Office of Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (emphasis added) ["OIG Pharma Guidance"]. The OIG has not issued specific compliance program guidance for distributors. However, the basic program elements discussed in the OIG Pharma Guidance are applicable to distributors as well.

[106] *See* FSGs 2004 at § 8B.2.1 (The "program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct.").

- Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.[107]

According to the OIG, while there are various ways to demonstrate a company's commitment to compliance, "[e]vidence of that commitment should include the allocation of adequate resources."[108] Therefore, "the compliance measures adopted ... should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience)," and "the compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully."[109] The 2017 compliance program effectiveness guidance documents from both the OIG and DOJ reiterate once more the importance of adequately resourcing the compliance function.[110]

### 6.2.1 Attributes

Within the context of a controlled substances compliance program, I would expect a good anti-diversion program for both a manufacturer and a distributor to have the following attributes:

1. **Integration:** The anti-diversion program is integrated into the overall fabric of the organization's corporate compliance program as directed by the Chief Compliance Officer ("CCO"). This can be evidenced by:
    a. Periodic reports from the Controlled Substances Compliance Team to the CCO, as well as mention of those efforts in the CCO's annual report to the Board of Directors.
    b. Participation in or periodic input to the Corporate Compliance Committee, either directly or through the appropriate functional leader (e.g., VP of Operations).
    c. Including an explicit controlled substances compliance expectation within the company's code of conduct.

2. **High-level individual:** The organization assigns responsibility and authority for the anti-diversion program to a relatively high-level individual or group including:

[107] *See id.* at §§ 8B.2.1(a)(2)(A) and(a)(2)(C).

[108] *See* OIG Pharma Guidance at 23732.

[109] *Id.* at 23732 and 23739.

[110] *See* HCCA-OIG Compliance Effectiveness Roundtable, Measuring *Compliance Program Effectiveness: A Resource Guide*, at 12 (Mar. 27, 2017), available at https://oig.hhs. gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf ["HCCA Effectiveness Guidance"]; U.S. Dep't of Just., Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs (Feb. 8, 2017), 2-3 https://www.justice.gov/criminal-fraud/page/file/937501/download ["DOJ Compliance Evaluation"].

a. Designating a Vice President level, but no lower than Senior Director, as the highest-ranking person in charge of the anti-diversion program.
b. If the program is assigned to someone with additional duties and responsibilities, using the company HR performance review process to assure that he or she understands the success of the anti-diversion program is a key component to their overall compensation package.
c. If the program is embedded in an operations group (as opposed to the Office of the Chief Compliance Officer), the creation of an independent reporting line to the CCO.
d. Compliance determinations by the high-level individual or group, including customer acceptance/termination and processing of "flagged" orders are appealable only to the CCO or the Compliance Committee, and their decision is final.
e. The organization maintains current, accurate organizational charts applicable to the anti-diversion program.

3. **Resources:** The organization provides adequate budget and headcount to carry out the activities of the anti-diversion program effectively.
    a. The budget allows for enough travel funds to conduct onsite visits and investigations and provides some funding to hire outside support as needed.
    b. If the company leverages indirect reports (e.g., using internal audit staff to conduct customer investigations), using the company HR performance review process to assure that the indirect reports understand that supporting the anti-diversion program is a key component to their overall compensation package.

## 6.3 Written Standards & Education

Having established written policies and procedures (standards) is fundamental to having an effective compliance program.[111] Written standards serve as the basis for instructing an organization's employees not only what tasks need doing (policy) but how they need to accomplish those tasks (procedure). Written standards also are important to ensure consistent outcomes are achieved from the processes the organization utilizes.

While the exact format of policies and procedures vary by organization, there are standard elements common to all policies and procedures, especially in the pharmaceutical industry.[112] From a compliance program effectiveness standpoint, scope (do the standards encompass what needs to be addressed?), clarity (are the standards understandable?), accountability (do employees know what they are accountable for and when they must involve the gatekeepers?), and accessibility (can employees find the officially approved standards to read them?) are primary factors in determining whether policies and procedures will be effective.[113]

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[111] *See* FSGs 2004 at § 8B.2.1(b)(1).

[112] *See*, *e.g.*, Margret Amatayakul, *Practical Advice for Effective Policies, Procedures*, 74 J. OF *AHIMA*.4: 16A-D (Apr. 2003), http://library.ahima.org/doc?oid=59451#.XBfhIfZFwuW. For a list of those standard elements, see Appendix B, Figure 1.

[113] *See* HCCA Effectiveness Guidance, at 3-4; DOJ Compliance Evaluation, at 3-4; *see also* ISO 9001:2015 (outlining the basic concepts of good document control).

The centerpiece of an organization's collection of written standards, which include company policies and operational procedures, is a core statement of ethical and compliance principles commonly referred to as the "Code of Conduct." The Code of Conduct is the statement of the organization's fundamental principles and values, as well as the expectation that employees will be committed to compliance.[114] A Code of Conduct, while not expressly required by the Federal Sentencing Guidelines, nevertheless has been a leading practice since the late 1990's, and is an important mechanism for a company "to communicate effectively its standards and procedures to all employees and other agents" because Codes of Conduct are "publications that explain in a practical manner what is required."[115] The OIG also has enshrined the need for a Code in its OIG Program Guidance.[116]

While established written policies and procedures are critical, just having them is not enough for a compliance program to be effective. An organization's employees must know that those standards exist (communication) and what is expected from each employee (training or education).[117] Communicating those standards and expectations is not a "once and done" proposition.[118] Because the compliance environment is dynamic with many moving parts (e.g., new hires, new regulations, new policies, new organizational structures, etc.), as well as the fact that people generally need to hear the information more than once to absorb it (e.g., the marketing rule of seven), good compliance functions generally expend significant resources on communication and training.

Furthermore, it is an industry leading practice to require employees to demonstrate mastery of the information being imparted in training (e.g., education) via a test or assessment. Passage of such an assessment provides some modicum of objective evidence that the trainee was effectively trained. The most rigorous programs, especially those using eLearning systems, require the trainee to successfully answer two or three questions after each section to progress and then to pass a final assessment at the end. For "live" or "real-time" training sessions, leading practice is to employ a "sign-in sheet" or some other mechanism to capture attendance. In both cases, the data on attendance and successful completion are normally maintained in an employee's training record, sometimes referred to as their "training jacket," which can be either a digital record or paper file.

### 6.3.1 Attributes

Within the context of a controlled substances compliance program, I would expect the written standards in a good anti-diversion program for both a manufacturer and a distributor to have the following attributes:

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[114] *See, e.g.,* OIG Pharma Guidance at 23733.

[115] *See* FSGs 2004 at § 8B.2.1(b)(4).

[116] *See, e.g.,* OIG Pharma Guidance at 23733.

[117] *See* FSGs 2004 at § 8B.2.1(b)(4). ("The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subdivision (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.").

[118] *Id.*

1. **Standard Elements:** The written standards incorporate the standard elements common to all policies and procedures in the written standards, including but not limited to Title, Purpose, Scope, Responsibilities, Effective Date, and Revision History.[119]
    a. Key terms (e.g., thresholds) are defined either directly in the written standards or via a separate glossary of terms.
    b. Employees can clearly determine what they will be held accountable for and when they must involve the gatekeepers.
    c. Where discretion is granted to gatekeepers, the standards define the criteria used in making those decisions.

2. **Document Control:** The written standards are developed, revised and approved utilizing a formal document control process.
    a. The process, at a minimum, tracks approvals, revisions and the reason for any changes.
    b. The process ensures that obsolete versions of the standards are withdrawn from use, but maintains withdrawn copies in an archive.
    c. Depending on the size of the organization, the document control process may be either paper-based or electronic.
    d. All archived versions of written standards are stored and maintained as essential compliance and business records.

3. **Publication:** The written standards are maintained in a form and location readily accessible to all employees.
    a. Depending on the size of the organization, publication may be either paper-based (e.g., a manual) or via electronic media such as a company intranet.

Education in a good anti-diversion program would have the following attributes:

1. **Acknowledgment of Standards:** Employees with controlled substances responsibilities acknowledge receipt and having "read and understood" the issued standards in a timely manner (e.g., 10 days).
    a. Those acknowledgments are collected, tracked, and follow-up occurs for missing or incomplete acknowledgments.

2. **Good Training Practices:** All employee education courses follow good training practices including:
    a. Depending on the size of the organization, the courses are delivered by face-to-face or eLearning methods.
    b. Courses follow the principles of good instructional design (e.g., limited duration, information not densely packaged, etc.).[120]
    c. Session attendance and overall completion are tracked, and follow-up occurs for missing records or incomplete training.

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[119] For a complete list of standard elements, see Appendix B, Figure 1.

[120] *See, e.g.*, Presentation Mike Kunkle, *Instructional Design Primer*, (Feb. 6, 2011), https://www.slideshare net/MikeKunkle/basic-instructional-design-principles-a-primer (last accessed Mar. 14. 2019). This is presentation is illustrative of the fact that information on good instructional design is widely and readily available.

d. Successful completion of the course by employees is based on an objective assessment or test demonstrating comprehension of the topics covered.
e. Failure to successfully complete a course after 2 or 3 attempts triggers additional follow-up and counseling by the employee's manager and compliance as assisted by HR.
f. Every employee has an accurate record of any educational courses completed during their career with the company that is maintained in a readily retrievable format (e.g., a "training jacket" or Learning Management System ("LMS") file).
g. The education record, at a minimum, contains course, title, and date, instructor name or LMS file name, and completion outcome (e.g., pass or fail).
h. All educational course materials and individual educational records are stored and maintained as essential compliance and business records.

3. **Controlled Substances Education:** Employees with responsibilities for controlled substances compliance complete required education courses.
   a. Education courses for newly hired employees are completed before the new employees can work alone.
   b. Refresher education courses are conducted on an annual basis.

4. **General Compliance Education:** All employees receive a level of periodic compliance education that includes how to raise questions, as well as reporting issues of suspected misconduct.

5. **Other Educational Methods:** The organization uses other means and methods (e.g., periodic newsletters, "email blasts," etc.) to routinely engage with employees and keep them abreast of impending changes to the anti-diversion program or to solicit employee feedback.

## 6.4 Monitoring, Auditing & Investigations

Detection or due diligence is at the heart of an effective compliance program.[121] This concept of detection involves three different but interrelated activities (monitoring, auditing, and investigations). Although sometimes used interchangeably, monitoring, auditing and investigations differ in scope and application, but do all ultimately involve looking for anomalous behavior or outliers that need correcting.[122]

Effective Suspicious Order Monitoring Programs also utilize all three concepts. However, unlike a general corporate compliance program, a SOM program does not simply involve monitoring, auditing and investigating

[121] *See* FSGs 2004 at § 8B.2.1(a)(1).

[122] Monitoring is a continuous, real or near-real time activity using established criteria to demonstrate adherence to specific standards. Audits are retrospective, "snapshots in time" to provide assurance that employees are adhering to the required process. Transactional testing is used in audits to verify that the process truly is being followed. Investigations involve examining specific circumstances or individuals to determine if breaches of company policies, procedures or the law have occurred.

internally to ensure the employees are following the prescribed standards, but also applies these activities externally to its customer base as part of the system of controls for preventing diversion.[123]

By reviewing the DEA regulations and general guidance letters provided to all registrants during the review period, it is possible to get a clear concept of what a successful SOM program should look like. Below is a summarized list of SOM requirements derived from those sources:

1. The customer must be "known" to determine that the customer can lawfully receive the shipment.[124]
2. There must be a designed system.[125]
3. It must be operational. [126]
4. It must identify suspicious orders of controlled substances. [127]
5. Orders can be suspicious because of: [128]
   a. unusual size;
   b. substantial deviation from a normal pattern; or
   c. unusual frequency.
6. Once a suspicious order is discovered,
   a. the local DEA Field Office must be informed,[129] and
   b. the order must be prevented from being filled until it can be ascertained that the order will not be diverted.[130]

Utilized correctly, the establishment of thresholds (a cap on the amount of controlled substances a customer can order in a set period) is an effective way to identify, but not confirm, suspicious orders. Once identified as suspicious, the reasonable, and required steps, include placing a "hold" or "stop notice" on the order to prevent the product from potentially being diverted, immediately notifying the appropriate DEA field office or DEA headquarters or immediately conducting an appropriate investigation to determine if the suspicious order is indeed a potential diversion situation.

Only after the investigation determines that the risk of diversion is not present, can the shipment be processed in the usual course. However, if the investigation determines that there is a risk of diversion, the order must not be filled, and the company should contemplate other appropriate steps for handling future shipment requests. Those steps include refusing to ship any more products to the customer, requiring the customer to provide independent assurance that a diversion situation is not present, or terminating the customer altogether.

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[123] *See* 21 C.F.R. §§ 1301.74 (a-b); DOJ Compliance Evaluation at 7 (third party management); James Arnold 6/2013 Presentation at 42-53; Presentation by G. Boggs, *State of Prescription Drug Abuse*, 39 (2013), MCKMDL00336833; *see also* McKesson, *McKesson Operations Manual for Pharma Distribution, Controlled Substances Monitoring Program*, 56 (Aug. 24, 2011), MCKMDL00000021 ("McKesson's responsibility is to "Know our Customer.").

[124] *See* 21 C.F.R. § 1301.74(a).

[125] *See* 21 C.F.R. § 1301.74(b).

[126] *See* 21 C.F.R. § 1301.74(b).

[127] *See* 21 C.F.R. § 1301.74(b).

[128] *See* 21 C.F.R. § 1301.74(b).

[129] *See* 21 C.F.R. § 1301.74(b).

[130] *See* DEA 6/12/2012 Letter at 2.

### 6.4.1 Attributes

#### A. Distributors

Within the context of a controlled substances compliance program, I would expect the monitoring, auditing, and investigations program for a robust distributor anti-diversion program to have the following attributes:

1. **Know Your Customer:** The distributor has and maintains current granular and specific knowledge about each retail pharmacy customer and their unique circumstances.
    a. Customer background information:
        i. Is collected on all customers, including national retail chains, before any product sales are made.
        ii. Is collected using a standard methodology (e.g., a questionnaire) that balances the need to see patterns and trends amongst similarly situated customers, with the flexibility to capture unique circumstances.
        iii. Includes more than DEA and state Board of Pharmacy licenses to include available internet or commercially obtainable information (e.g., GOOGLE searches, Dun & Bradstreet reports, IMS data, etc.).
        iv. Includes dispensing data and largest prescribers.
        v. Includes whether the relationship is primary (e.g., exclusive) or secondary.
        vi. Includes the customer's prior overall compliance history that is not limited to just controlled substances.
        vii. Uses a risk-adjusted process for periodically re-evaluating customers considering changed circumstances. Those risk factors include the indicators of diversion provided by the DEA as well as changes in control (e.g., merger, acquisition, the sale of a business) or customer profile (e.g., new pain clinic in the territory served).
        viii. Obtains references from the primary distributor when known.
        ix. Is kept current and updated on a regular, periodic basis.
    b. Customer background information is evaluated for completeness and accuracy.
        i. Submissions of inaccurate or incomplete information are grounds for immediate disqualification or termination.
        ii. Refusal to provide requested background information is grounds for immediate disqualification or termination.
        iii. In the case of the large retail pharmacy chains (e.g., CVS, Walgreens, and Rite Aid) defines "customer" in terms of the individual retail pharmacy location and not just the national chain.
    c. Customers are evaluated and approved or denied based upon submitted background information and any other due diligence conducted by the organization.
        i. Evaluations occur under established criteria, which, at a minimum, incorporate any guidance from the DEA.
        ii. "Red flags" such as being a secondary supplier or customer being recently terminated by another distributor trigger a thorough investigation including a site visit by a trained investigator.
        iii. Outcomes are clear and well-documented.

d. Customer site visits are routinely and periodically performed even after an initial site visit.
    i. Site visits are performed by individuals trained in diversionary behaviors.
    ii. If sales personnel are utilized to perform site visits, steps are taken to minimize conflicts of interests (e.g., using out-of-territory personnel).
e. Customer files are stored and maintained as essential compliance and business records.

2. **Thresholds:** The organization uses threshold calculations based on dosage units to identify "suspicious orders."
    a. Thresholds are customer-specific and set using the background information obtained and maintained by the organization in accordance with the organization's written standards.
    b. Like customers are grouped together with as much granularity as possible (e.g., business activity, purchasing patterns, total prescriptions, geographic location, size of territory served).
    c. Thresholds are calculated based on multiple criteria using a documented, validated statistical formula that considers, at a minimum, the following items:
        i. Customer group;
        ii. Order size, patterns, and frequency, both individually and of the group; including orders being filled by other distributors;
        iii. Dispensing data, both individually and of the group;[131]
        iv. Geographic territory and population served;
        v. Product formulation (active ingredient and dosage) as well as the diversion potential; and
        vi. Legitimate, medically necessary, dosage unit levels developed based upon the approved indications for use and without regard to current opioid purchasing patterns.
    d. A minimum of 12-months of relevant and complete historical data is used without "cherry picking" the most favorable data.
    e. Actual thresholds and the threshold calculation methodology are not shared with customers.
    f. Thresholds are binding until an approved threshold exception or adjustment is granted.

3. **Threshold Exceptions or Adjustments:** Any threshold exceptions or adjustments rarely are made when viewed by the individual customer or the group, as well as a simple review of request frequency.
    a. Threshold exceptions or adjustments are made by a committee of individuals with anti-diversion experience and training in accordance with the organization's written standards.
    b. All threshold exceptions or adjustments are supported by verifiable objective evidence that is documented in writing.
    c. Threshold exceptions and adjustments are tracked and trended on both a short-term (e.g., weekly or monthly) and long-term (e.g., quarterly or annual) basis.
    d. All threshold exceptions or adjustments, including any records of approvals or denials, are stored and maintained as essential compliance and business records.

4. **Taking Action:**

[131] With the appropriate safeguards to protect patient identifiable health information under HIPPA and other relevant privacy standards.

a. All orders which exceed the customer-specific threshold are deemed "suspicious" and reported to the DEA within one week unless it is determined that there are no reasons to suspect that a customer is engaging in diversion; for example, a clerical mistake (e.g., "fat-finger" orders).
b. All orders exceeding thresholds are held and not shipped. No order "cutting" is permitted.
c. No orders exceeding thresholds may ship until a thorough independent investigation is completed based on verifiable objective evidence demonstrates that diversion is unlikely to occur, and the findings are reviewed and approved.
    i. The use of the Corporate Headquarter staff of the large retail pharmacy chains (e.g., CVS, Walgreens, and Rite Aid) as the "lead investigator" is not permitted to maintain independence.
d. No future orders involving the same active ingredient are processed or shipped until the thorough independent investigation is completed based on verifiable objective evidence that demonstrates diversion is unlikely to occur and the findings are reviewed and approved.

5. **Audits:** The distributor's internal audit team, or an appropriately qualified third-party (e.g., the company's external auditors) conducts periodic, regular audits of the distributor's anti-diversion program including transactional testing of a statistically relevant sample of retail pharmacy customers.
    a. All customer supply contracts contain the appropriate "right-to-audit" clause.
    b. All audits are conducted in accordance with written standards.
    c. Audits are conducted on a risk-adjusted basis.
    d. Audit findings and corresponding management responses are tracked and trended.
    e. Repeat audit findings are escalated to the organization's Chief Executive Officer and the Audit Committee of the Board of Directors.

## B. Manufacturers

For a manufacturer's anti-diversion program, I would expect to see:

1. **Know Your Customer:** The manufacturer has and maintains current granular and specific knowledge about each distributor of its controlled substances and their unique circumstances including all the information outlined in the distributor section above.
    a. Distributor site visits are undertaken to review the distributor's anti-diversion controls both at initiation of the relationship and then periodically on a risk adjusted basis thereafter (see Audits section below).
    b. Utilize, where appropriate, information derived from chargeback data.

2. **Individual Retail Pharmacy Activity:** Like the distributor thresholds outlined above, the manufacturer establishes ordering levels for specific pharmacies, which if exceeded trigger the manufacturer to be concerned that the orders are "suspicious," and that action is needed.
    a. Where appropriate, information obtained through the manufacturer's sample accountability (e.g., PDMA) program is factored into the controlled substances monitoring program.
    b. Wherever possible, the manufacturer leverages synergies (people, process and technology) between the sample accountability and controlled substances compliance programs.

3. **Taking Action:** When the manufacturer gains knowledge of retail pharmacies placing "suspicious orders" or otherwise engaging in diversionary behavior (e.g., serving questionable prescribers), the manufacturer takes the following actions:
    a. The manufacturer notifies and provides details of the suspicious activity to both the DEA and the distributor.
    b. The manufacturer demands the distributor, and any secondary distributor if known, follow-up and take appropriate action regarding the highlighted pharmacies.
    c. The manufacturer maintains contact with the distributor, and any secondary distributor if known, requiring them to provide details on the outcome of any investigations including actions taken by the distributor(s) against the pharmacies.

4. **Audits:** The manufacturer conducts both routine and "for cause" audits of those distributors' anti-diversion programs.
    a. All customer supply contracts contain the appropriate "right-to-audit" clause.
    b. Routine audits are conducted on a risk-adjusted basis.
    c. All audits are conducted in accordance with written standards.
    d. Audit findings and corresponding management responses are tracked and trended.
    e. Repeat audit findings are escalated to the organization's Chief Executive Officer and the Audit Committee of the Board of Directors.

## 6.5 Corrective Actions & Risk Assessments

Once non-compliant conduct, whether criminal or not, has been detected by monitoring and confirmed to have occurred through investigation, the organization is expected to determine and implement changes to avoid either a continuation of the underlying conduct, or to prevent a new occurrence from arising.[132] As the OIG elaborated:

> Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. **Detected but uncorrected misconduct can endanger the reputation and legal status of the company**.
>
> Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and if so, take **decisive steps** to correct the problem.[133]

[132] *See* FSGs 2004 at § 8B.2.1(b)(7) ("After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.").

[133] *See* OIG Pharma Guidance at 23742 (emphasis added); HCCA Effectiveness Guidance at 50-51 §§ 7.43-7.54.

The DEA regulations also embody the corrective action concept.[134] Identified corrective actions need to be documented and monitored to ensure they are implemented. This is especially true for complex corrective actions that often span many weeks or months to accomplish.

For a compliance program to be effective, just correcting errors, omissions and breaches are not enough. Organizations also need a documented process to conduct risk assessments.[135] The risk assessment process captures changes as various risks morph (e.g., the emergence of internet pharmacies dispensing controlled substances), as well as what the organization is doing to address or mitigate those risks and to assess whether those activities are working.[136]

Typically, when companies first embark on establishing a compliance program, they engage in a risk assessment, more often referred to as a "gap analysis." This gap analysis provides the compliance program designers with crucial information on what needs to be addressed.

However, risk assessments normally are not a single event. The risk assessment process envisioned by the FSGs is a true, repeatable process that should occur at regularly scheduled intervals. Therefore, while the gap analysis is usually done at the beginning, the formal risk assessment process frequently is established after the basic compliance program framework is in place.

### 6.5.1 Attributes

Within the context of a controlled substances compliance program, I would expect the corrective action and risk assessment processes for both a robust distributor and manufacturer anti-diversion program to have the following attributes.

1. **Corrective Actions:** The organization has a formal, documented corrective action process, and applies that process to the anti-diversion program:
    a. All program deficiencies are documented regardless of source (e.g., internal or external audits, internal or external assessments, regulatory inspections, regulatory guidance, and industry standards).
    b. For every documented deficiency, a plan for correction, which details the remedy, employees' responsible for making the corrections and plan milestones, is developed.
    c. The final approved plans are collected and tracked with corresponding updates to the Compliance Committee, Senior Management and if warranted the Audit Committee of the Board of Directors.
        i Whenever possible, corrective action documentation and tracking are incorporated into the organization's electronic Governance, Risk and Compliance or e GRC system (e.g., Archer).

[134] *See, e.g.*, 21 C.F.R. § 1301.71(c).

[135] *See* FSGs 2004 at § 8B.2.1(c) ("In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.").

[136] *See* DOJ Compliance Evaluation at 4-5, Topic 5; HCCA Effectiveness Guidance, at 15 §§ 2.56-2.62.

d. Plan timelines have a finite time limit (e.g., no more than 12 months)
    i If additional time is necessary to complete the corrective action, a new plan is submitted and approved.
    ii Senior Management and Compliance approval is required for any extensions.
e. Individual accountability is managed through the standard HR performance appraisal process.
f. Corrective action items are only closed upon independent verification that the planned corrections are complete and functioning as intended.

2. **Risk Assessments:** The organization maintains a formal, documented risk assessment process to evaluate legal and compliance risks to the organization's anti-diversion program. A robust process includes, but is not limited to, the following elements:
    a. The process evaluates both internal and external risks to the anti-diversion program.
    b. The process leverages data from all available sources, including but not limited to:
        i Budgets;
        ii Headcount;
        iii Exit interviews;
        iv Employee surveys;
        v Investigation results;
        vi Audit results;
        vii Corrective actions;
        viii Commercial benchmarking data (e.g., IMS data);
        ix Regulatory inspections; and
        x Enforcement actions.
    c. A risk assessment review occurs at defined intervals, but no less than annually.
    d. The risk assessment output is documented and is:
        i Disseminated widely to management, compliance, legal, internal audit and those responsible for the anti-diversion program.
        ii Maintained in a readily digestible format such as a "heat map."
        iii Incorporated, whenever possible into the organization's eGRC system.
        iv Used to develop further corrective actions, audit planning, budget and headcount increases, customer monitoring efforts, etc.
    e. Previous risk assessment outputs are maintained and utilized for benchmarking and trending purposes to show improvement or decline in the effectiveness of the anti-diversion program.

## 6.6 Accountability - Consistent Enforcement

Accountability also is a fundamental element of an effective compliance program. Under the FSGs, there are two intertwined provisions that apply in this context. The first involves consistent enforcement of compliance

and ethical standards, including government requirements, otherwise known as discipline.[137] The second involves being careful with the delegation of substantial authority, otherwise known as "avoiding bad actors."[138]

### 6.6.1 Discipline

In the case of consistent enforcement, the FSGs succinctly notes "[a]dequate discipline of individuals responsible for an offense is a necessary component of enforcement."[139] The OIG Compliance Program Guidance goes further stating:

> Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. **Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct**.[140]

### 6.6.2 Avoiding "Bad Actors" – Employees or Customers

The FSGs also requires organizations to "use reasonable efforts" to ensure that "with the substantial authority personnel of the organization any individual whom the organization knew or should have known through the exercise of due diligence, has engaged in illegal activities or **other conduct inconsistent with an effective compliance and ethics program**" are not placed in a position to cause harm through their non-compliant actions. [141]

The FSGs defines "substantial authority personnel" as:

> individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of an organization. The term includes high-level personnel of the organization, individuals who exercise substantial supervisory authority (e.g., **a plant manager, a sales manager**), and any other individuals who, although not a part of an organization's management, nevertheless exercise substantial discretion when acting within the scope of their authority (e.g., an individual with **authority** in an organization **to negotiate or set price levels** or an individual authorized to negotiate or approve significant contracts).[142]

While the FSGs focuses primarily on organizational and employee accountability, the CSA and its implementing regulations focus on customer behaviors. Embedded within the concept of identifying suspicious orders and having effective diversion controls is the common sense proposition that if an order is initially

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[137] *See* FSGs 2004 at § 8B2.1(b)(6).

[138] *See* FSGs 2004 at § 8B2.1(b)(3).

[139] *See* FSGs 2004 at § 8B2.1, Application Note 5.

[140] *See* OIG Pharma Guidance at 23742 (emphasis added).

[141] *See* FSGs 2004 at § 8B2.1(b)(3) (emphasis added).

[142] *See* FSGs 2004 at § 8A1.2, Application Note 3(c) (emphasis added).

flagged as suspicious using the criteria in the DEA regulations (unusual size, pattern, frequency), the distributor must not ship that order or any similar controlled substances order to that customer until the distributor determines whether or not there is likelihood the shipment is being diverted.[143] To do otherwise, potentially allows a diversionary situation to continue, which is the opposite of preventing diversion.[144] In other words, the distributor is expected to impose discipline on its customers when the distributor becomes aware of customers that are placing suspicious orders.

### 6.6.3 Attributes

1. **Employees:** The organization (both distributors and manufacturers) maintains a robust screening (background check) process and a disciplinary system that includes appropriate sanctions up to and including termination.
    a. Employees alleged to have violated any anti-diversion requirements are immediately removed from any further responsibilities involving controlled substances until cleared by a thorough independent investigation demonstrating that no violation occurred based on verifiable objective evidence.
    b. Employees who violate the requirements of the organization's anti-diversion program are subject to appropriate disciplinary sanctions.
    c. Disciplinary sanctions are routinely and consistently enforced regardless of an employee's level in the organization or previous job performance.

2. **Distributor Customers:** Retail pharmacy customers, failing to comply with any requirements of the distributor's anti-diversion program (e.g., providing incomplete or inaccurate information) are subject to immediate disqualification or termination.
    a. This requirement is explicitly stated in all customer supply contracts.
        i. Contracts contain a "for cause" immediate termination provision, which includes being non-compliant.
    b. Disqualifications and terminations are routinely and consistently enforced regardless of a customer's prior purchasing history.
    c. Any pending shipments are immediately canceled.
    d. Disqualified or terminated customers are not eligible for reinstatement until a thorough audit is conducted and any corrective actions by the customer are verified via objective evidence demonstrating that the customer has effectively corrected all issues underpinning the disqualification or termination.

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[143] DEA 2/7/2007, 12/27/2007, 6/12/2012 Letters at 2; *see also Southwood Pharmaceuticals, Inc.*, Revocation of Registration, 72 Fed. Reg. 36487, 36500 (Jul. 3, 2007) (Holding the distributor accountable for not stopping shipments to customers it should have known were placing suspicious orders including those customers DEA told the distributor were engaging in suspicious ordering).

[144] *See* 72 Fed. Reg. at 36500 ("In short, the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone. Indeed, it is especially appalling that notwithstanding the information the Respondent received from both this agency [DEA] and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies. Moreover, in several cases, Respondent actually distributed even larger quantities of the drug to them.")

i. Reinstatement of disqualified or terminated customers is reviewed and approved by either the CCO or Compliance Committee.

e. Notices of customer disqualifications or terminations are communicated as soon as possible to the distributor's sales representatives.
   i. The distributor adjusts sales representative compensation plans to remove any negative impact from disqualification or termination.

3. **Manufacturer Customers**: Distributor customers of the manufacturer, which distribute the manufacturer's prescription opioid products are subject to appropriate disciplinary sanctions up to and including termination of the relationship.
   a. This requirement is explicitly stated in all customer supply contracts.
      i. Contracts contain a "for cause" immediate termination provision, which includes being non-compliant either with the manufacturer's anti-diversion requirements or when cited by the DEA.
   b. Contracts allow for the immediate cessation of chargebacks for prescription opioid products to non-compliant retail pharmacy customers.

## 6.7 Manufacturer – Prescriber Relationship

Opioid manufacturers within the DEA's "closed-loop" system, unlike distributors, also are uniquely positioned to observe prescriber behaviors. This occurs because the manufacturers' field forces make routine sales calls on prescribers' offices. Thus, the field forces can be exposed to some of "red flag" indicators such as overly full waiting rooms, young patients, people nodding off in the waiting room, etc.[145] Put another way, things that "if you were to walk into a doctor's office would give you pause and would make you turn around and walk out."[146] The same is true for information obtained from other sources such as IMS data, or media reports.

Given this unique vantage point, the prudent and responsible manufacturer should instruct and require its sales representatives, and in-house field support and marketing personnel, to provide any observations of potential diversionary behavior to their in-house Compliance Department for further evaluation and potential action. As Acting Administrator Rosenberg noted in the Masters Pharmaceutical proceedings, "a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices" or more specifically, "a registrant cannot claim that it … has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices."[147] While the company needs to act with care to be objective (which is true for every compliance investigation), "turning a blind eye" is not an option.

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[145] *See* Scott Glover and Lisa Giron, OxyContin maker closely guards its list of suspect doctors, LOS ANGELES TIMES (Aug. 11, 2013), https://www.latimes.com/local/la-xpm-2013-aug-11-la-me-rx-purdue-20130811-story html.

[146] *See id.* (quoting Robin Abrams, attorney for Purdue Pharma and a former federal prosecutor specializing in federal healthcare fraud).

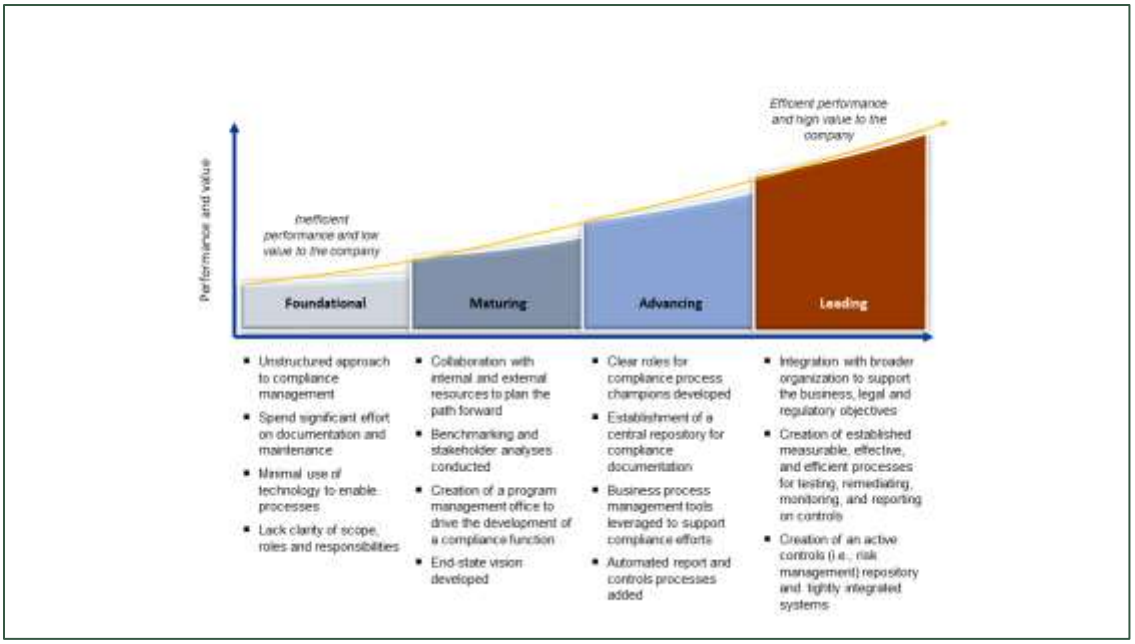
[147] *See* 80 Fed. Reg. 55418, 55478 (Sept. 15, 2015).

Upon receipt of this information, the Compliance Department, or other experienced investigators, should conduct an appropriate investigation to determine the validity of the information, using all available sources of information (e.g., the internet, IMS data, etc.), and if confirmed, formulate an appropriate action plan. Depending on the weight of the evidence gathered, that plan can range from conducting further comprehensive monitoring activities to refusing to make further sales calls on the suspect practices to, in the most egregious cases, providing the information to the appropriate authorities, including the DEA and State Medical Boards.

# 7 Measuring What Good Looks Like

After defining "what good looks like" the next step is to measure it. Measuring compliance effectiveness or "what good looks like" is not simply a matter of taking the attributes and applying a statistical, or even a generally recognized standard scoring methodology, as one does not exist. The best approximation of a standardized scoring model is the compliance maturity and program effectiveness model, which outlines the typical evolutionary pathway most compliance organizations follow.

**Figure 2– Compliance Maturity & Program Effectiveness Model**




The model sets out a framework outlining what characteristics distinguish a compliance function that is just starting out or where management does not embrace the value of the program from one which is fully embedded into company operations and where management clearly recognizes the value that strong compliance provides. Since the levels of maturity directly correlate to the effectiveness of the compliance program, this model also provides a way to level-set among companies in the same field (e.g., pharmaceutical distribution). Overall, most companies focus on and strive to be in either the advancing or leading categories.

This report first analyzes each distributor's and a single manufacturer's overall compliance efforts surrounding controlled substances by starting with suspicious order monitoring. For each company, the analysis focuses on answering two questions. The first question is whether objective evidence exists supporting that the company

being reviewed worked to establish a suspicious order monitoring system, as well as controlled substances and corporate compliance programs. Only if there is evidence that the company did so is the second question relevant.

The second question is whether there is objective evidence showing that the company met its three-prong program effectiveness requirement by (a) having a program that prevents and detects criminal conduct by an organization's employees and (b) maintaining effective controls against diversion, including (c) maintaining and operating an effective system to identify, hold, investigate and report suspicious orders of controlled substances.

# PART IV: Report Overview

## 8 Executive Summary

### 8.1 Group 1 Distributors

The Group 1 ("G1") distributors (also known as the "Big Three"), on a national basis, account for 85% of the national drug supply.[148] Although each G1 distributor's detailed approach to both corporate compliance and anti-diversion controls for controlled substances was reviewed separately, there are common threads that unite all three companies.

[148] *See* W.Va. Red Flags Report at 7.

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# DR. SETH B. WHITELAW

## PROFESSIONAL SUMMARY

Dr. Whitelaw has more than 25 years of industry experience in the life sciences and healthcare sectors, as an attorney, compliance officer and consultant. His career has focused on food and drug law and corporate governance, as well as designing and running compliance programs within medical devices, pharmaceutical sales and marketing, and pharmaceutical R&D. He is a licensed food and drug attorney, with a doctorate in Health Law. His forte is designing, building and running life science compliance programs from a "blank sheet of paper."

## LICENSES & INTERNSHIPS

Licensed to Practice Law in the Commonwealths of Pennsylvania (2004) and Virginia (1988)

Food and Drug Law Institute Fellowship (1988)

Internship with U.S. Food and Drug Administration, Office of Chief Counsel (1988-1989)

Internships with Grocery Manufacturers Association (GMA), Washington, D.C.

## EXPERIENCE

**WHITELAW COMPLIANCE GROUP, LLC., PHILADELPHIA, PA**
**President & CEO, April 2015 – Present**

Focused exclusively on small to medium-sized FDA-regulated companies, the Whitelaw Compliance Group provides practical, pragmatic compliance and integrity services that are tailored to each regulated company to help them grow and achieve sustainable integrity.

Responsible for designing, developing and implementing a med tech tailored compliance program to address compliance risks, including FCPA and UK Bribery Act issues.

**POLICY & MEDICINE COMPLIANCE UPDATE, COLUMBIA, MD**
**Editor, October 2015 – Present**

Formerly Life Science Compliance Update. Oversees the editorial content, assembly and monthly publication providing comprehensive, up-to-date compliance information for pharmaceutical, biotechnology, and device manufacturers. Writes articles on emerging life sciences issues for the publication.

**MITCHELL HAMLINE SCHOOL OF LAW, ST. PAUL, MN**
**Senior Fellow and Adjunct Professor, Life Sciences Compliance, September 2016 – Present**

Oversaw, designed and taught Legal Compliance Essentials for Drug, Device and Biotech Companies (J-Term 2017)

Co-teaching Health Care Compliance Skills (Fall 2017 & Spring-Fall 2018)

**MISONIX, INC., FARMINGDALE, NY**
**Interim Chief Compliance Officer, December 2016 – June 2017**

Interim Chief Compliance Officer for Misonix, Inc., which specializes in the development and commercialization of ultrasonic surgical devices for neurosurgical, spinal, advanced wound care, and general surgery procedures. Responsible for the day-to-day implementation and operation of the Compliance Program including compliance efforts involving interactions with health care professionals and anti-bribery/anti-corruption.

- Delivered over $165K in sales, from Chinese distributors as a result of overseeing and managing enhanced third-party due diligence and contracting process.

**DELOITTE & TOUCHE LLP., PHILADELPHIA, PA**
**Director, October 2011 – April 2015**

Led the Advisory Practice's transparency team assisting U.S. and other global medical device and pharmaceutical clients in developing effective processes and operating approaches to meet both U.S. Sunshine Act requirements, as well as other global requirements (e.g., France, Japan and EFPIA).

- Consistently delivered more than $1M in sales each year.

Advised various multinational clients on structuring a global compliance function including work plan prioritization.

Assisted a client with medical device, pharmaceutical, and consumer products units to develop a streamlined and strategic Medical Affairs department to support its globally growing business.

Conducted multiple internal audits for clients in both the R&D and third-party oversight areas working with global teams.

Served as Editor-in-Chief and contributing author for Deloitte's @Regulatory bulletins from 2013-2015

**GLAXOSMITHKLINE, PHILADELPHIA, PA**
**Compliance Officer, Global R&D, January 2001 – October 2011**

Successfully designed, developed, implemented and led the corporate compliance infrastructure, including integrating internal audit with compliance, for GSK's global R&D operations where none had existed previously.

Founded and supported the compliance infrastructure for GSK's new R&D China site in Shanghai.

Provided compliance oversight and support to sites in U.S, U.K. China, Italy, Spain, France and Croatia with small (9) central staff on a broad range of topics including conflicts of interest, anti-kickback, FCPA, false claims, use of human biological samples, transparency, etc.

Created and implemented policies, systems and processes ahead of industry practice to reduce the risk from perceived improper influence with healthcare professionals, especially in countries with national health insurance programs.

Successfully negotiated with various regulatory authorities to resolve compliance issues.

Led compliance efforts surrounding GSK's voluntary disclosure of research payments to healthcare professionals and healthcare institutions (e.g., transparency).

Helped lead R&D's efforts to prepare for impending Corporate Integrity Agreement

**SMITHKLINE BEECHAM PHARMACEUTICALS, PHILADELPHIA, PA**
**Legal Compliance Officer, January 1997 – January 2001**

Successfully designed and implemented the corporate compliance infrastructure for the U.S. and Canadian commercial operations where none had existed previously and co-led the integration of the departments during the Glaxo Wellcome/SmithKline merger.

Created and implemented policies, systems and processes ahead of industry practice to reduce the risk from perceived improper influence with healthcare professionals (e.g., banning gifts).

Successfully help lead the efforts to enhance SmithKline's sample accountability (PDMA) program.

**C.R. BARD, INC., MURRAY HILL, NJ**
**Senior Attorney & Compliance Coordinator, January 1991 - January 1997**

Created and implemented Bard's original corporate medical device compliance program to meet the requirements of the Federal Sentencing Guidelines and Bard's Plea Agreement with the U.S. Department of Justice and served as Bard's first Compliance Officer post settlement.

Successfully directed and managed Bard's company-wide document production efforts for the U.S. v. C.R. Bard, Inc. litigation resulting in the production of over 750,000 responsive pages. Worked directly with both the AUSA's Office in Boston as well as FDA's Office of Criminal Investigation.

Oversaw and updated Bard's records retention program.

Created, managed and implemented a Legal Audit Program to provide the Corporation with a concrete evaluation of its overall compliance with both the federal FDA regulatory scheme (e.g., 501(k) compliance, Quality System requirements) and its internal policies. This program was successfully integrated with Bard's already established internal and quality auditing programs.

Provided legal counsel on various medical device regulatory matters including those issues involving FDA, EPA and OSHA (e.g., custom devices, consumer preference testing, medical device reports, FDA-483 and Warning Letter responses)

**FD Inc., Washington, D.C.**
**Head of Sales and Marketing, March 1990- January 1991**

Sales and marketing of food and drug statutory, administrative and regulatory materials on compact disk, with direct responsibility for developing and implementing both short and long-term marketing strategies for the company.

**Fox, Bennett & Turner., Washington, D.C.**
**Associate, May 1989- March 1990**

Compliance counseling and opinion drafting on food, drug and environmental issues, particularly safety and risk assessment.

EDUCATION

**WIDENER UNIVERSITY SCHOOL OF LAW, WILMINGTON, DE**
2011 – S.J.D., Health Law

**GEORGE WASHINGTON UNIVERSITY LAW SCHOOL, WASHINGTON, D.C.**
1989- LL.M., Administrative Law

**WASHINGTON & LEE UNIVERSITY, SCHOOL OF LAW, LEXINGTON, VA**
1988 – J.D.

**BOWDOIN COLLEGE, BRUNSWICK MAINE**
1985- A.B., History (*Cum laude)*

Publications List

*PUBLICATIONS*

- Whitelaw, Seth; Fiorentino, Nicodemo; and O'Leary, Jennifer "Drug Pricing—The Next Compliance Waterloo," Mitchell Hamline Law Review: 2018 Vol. 44: Iss. 4, Article 2. Available at: https://open.mitchellhamline.edu/mhlr/vol44/iss4/2.
- Schroeder, Whitelaw, Makosch, Adapt or Perish -Can Stem Cell Therapies Achieve Their Potential for Delivering Optimal, Cost-Effective Clinical Outcomes in an Evolving Regulatory Framework?, Life Science Compliance Update Special Supplement (Aug. 2018)
- Whitelaw, et al., The Day After Tomorrow - The Drug Pricing Chorus Grows Louder, 4.4 Life Science Compliance Update 1 (Apr. 2018)
- "Missing the Market: Government Standards Are Undermining Compliance Efforts in Smaller Life Science Companies," Attorney at Law Magazine, Minnesota Ed. (Mar. 2018)
- Whitelaw, et al., A Bright Future or Unfulfilled Promise – An Update on Biosimilars and Their Prospects for Contributing to Meaningful Cost Reduction, 4.3 Life Science Compliance Update 13 (Mar. 2018).
- "One Purpose to Rule Them All – A Resounding 'Yes' According to the District Court in U.S. ex rel. Cairns," Life Science Compliance Update, Vol. 4.2 (Feb. 2018).
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- "Proposition 65 v. Industry: David Against Goliath or a Misled Public Run Amok?," 44 Food Drug Cosmetic Law Journal 677
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- "Time Crunch - Physician Payments Sunshine Act," Deloitte (Jun. 2013) (http://www.deloitte.com/view/en_US/us/Services/audit-enterprise-risk-services/governance-regulatory-risk-strategies/9a0af1b41c08f310VgnVCM1000003256f70aRCRD.htm)
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- Practicing Avoidance: Navigating Qui Tam and Consent Decrees, Pharmaceutical Compliance Monitor (Jan. 9, 2012), http://www.pharmacompliancemonitor.com/practicing-avoidance-navigating-qui-tam-consent-decrees/#more-996.
- How Can FDA Improve Its Financial Disclosure Rules for Clinical Investigators in this New Era of Transparency?, Food and Drug Law Institute Policy Forum (June 2011)

*ONLINE CONTENT (EDITOR)*

- Policy & Medicine Compliance Update Vol. 5.4 April 2019.
- Policy & Medicine Compliance Update Vol. 5.3 March 2019.
- Policy & Medicine Compliance Update Vol. 5.2 February 2019.
- Policy & Medicine Compliance Update Vol. 5 January 2019.
- Policy & Medicine Compliance Update Vol. 4.12 December 2018.
- Policy & Medicine Compliance Update Vol. 4.11 November 2018.
- Policy & Medicine Compliance Update Vol. 4.10 October 2018.
- Policy & Medicine Compliance Update Vol. 4.9 September 2018.
- Adapt or Perish Can Stem Cell Therapies Achieve Their Potential For Delivering Optimal Cost-Effective Clinical Outcomes In an Evolving Regulatory Framework?, Policy & Medicine Life Science Compliance Special Supplement Vol. 4.8 August 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.8 August 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.7 July 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.6 June 2018.
- Policy & Medicine Life Science Compliance Update Vol. 4.5 May 2018.

- Policy & Medicine Life Science Compliance Update Vol. 4.4 April 2018.
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- Policy & Medicine Life Science Compliance Update Vol. 3.8 August 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.7 July 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.6 June 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.5 May 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.4 April 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.3 March 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.2 February 2017.
- Policy & Medicine Life Science Compliance Update Vol. 3.1 January 2017.
- Policy & Medicine Life Science Compliance Update Vol. 2.12 December 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.11 November 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.10 October 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.9 September 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.8 August 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.7 July 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.6 June 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.5 May 2016.
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- Policy & Medicine Life Science Compliance Update Vol. 2.3 March 2016.
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- Policy & Medicine Life Science Compliance Update Vol. 2.1 January 2016.
- Policy & Medicine Life Science Compliance Update Vol. 2.0 December 2015.
- Policy & Medicine Life Science Compliance Update Vol. 1.9 November 2015.

- Compliance for the Common Man Policy & Medicine Life Science Compliance Update Vol. 1.5 July 2015.

*REPRESENTATIVE SPEAKING ENGAGEMENTS*

- Guest lecturer at Temple University, Ursinus College, Medical Devices Section, Food and Drug Law, Rutgers-Camden Law School
- Mitchell Hamline's Health Law Institute Symposium - Hot Topics in Healthcare Compliance (2018)
- CBI 2nd Annual Drug Pricing Transparency Conference (2018)
- CBI Annual Pharmaceutical Compliance Congress (multiple years) Pharmaceutical Regulatory and Compliance Congress (multiple years)
- Mitchell Hamline School of Law, National Speaker Series (Oct. 2016)
- DIA Marketing Pharmaceuticals (2014)
- Sixth National Disclosure Summit (2014)
- Pharmaceutical Regulatory and Compliance Congress (2013)
- Food and Drug Law Institute Advertising and Promotion Conference (2013)
- CBI 9th Annual Pharmaceutical Accounting and Reporting Congress (2013)
- AdvaMed Conference (2012)
- CBI 9th Annual Pharmaceutical Compliance Congress (2012)
- FDLI US-China Food and Drug Law (2011)
- Food and Drug Law Institute Annual Conference (2011)
- ACI 11th National Forum on Fraud & Abuse in Sales & Marketing (2011)
- Widener Law 2d Annual Regulatory Compliance Program (2010)
- Marcus Evans Commercial Compliance for Pharmaceutical & Medical Device Companies (2010)
- CBI Clinical R&D Compliance Forum (2010)
- Drug Information Association 46th Annual Meeting (2010)
- Pharma Compliance Forum (2009 & 2010)
- ACI Medical Affairs Conference (2009)

## Prior Testimony

None.